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107TH CONGRESS
1ST SESSION

H. R. 526

To amend the Public Health Service Act, the Employee Retirement Income Security Act of 1974, and the Internal Revenue Code of 1986 to protect consumers in managed care plans and other health coverage.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 8, 2001

Mr. GANSKE (for himself, Mr. DINGELL, Mr. LEACH, Mr. BERRY, Mrs. ROUKEMA, Mr. BROWN of Ohio, Mrs. MORELLA, Mr. JOHN, Mr. GILMAN, Mr. ANDREWS, Mr. LATOURETTE, Mr. RANGEL, Mr. STENHOLM, Mr. SANDLIN, Mr. STUPAK, Mr. PALLONE, Mr. TOWNS, Ms. ESHOO, Mrs. CAPPS, Mr. GREEN of Texas, Mr. GORDON, Ms. MCCARTHY of Missouri, Mr. ENGEL, Mr. MOORE, Mr. STICKLAND, Mr. MARKEY, Mr. SAWYER, Mrs. DAVIS of California, Mr. BARRETT, Mr. WYNN, Mr. STARK, Mr. WAXMAN, Mr. RUSH, Mr. BOUCHER, Mr. HALL of Texas, Mr. BISHOP, Mr. TURNER, Ms. HARMAN, Mr. PASCRELL, Mrs. MCCARTHY of New York, Mr. FRANK, Mr. MATSUI, Mr. COYNE, Mr. MCDERMOTT, Mr. CARDIN, Mr. LEVIN, Mr. MCNULTY, Mr. JEFFERSON, Mr. BECERRA, Mr. LEWIS of Georgia, Mr. KLECZKA, Mrs. THURMAN, Mr. BOSWELL, Mr. CROWLEY, Mr. TIERNEY, Mr. HOEFFEL, and Mr. MEEHAN) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Education and the Workforce, and Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To amend the Public Health Service Act, the Employee Retirement Income Security Act of 1974, and the Internal Revenue Code of 1986 to protect consumers in managed care plans and other health coverage.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Bipartisan Patient Protection Act of 2001''.

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

TITLE I—IMPROVING MANAGED CARE

Subtitle A—Utilization Review; Claims; and Internal and External Appeals

SEC. 101. UTILIZATION REVIEW ACTIVITIES.

(a) COMPLIANCE WITH REQUIREMENTS.—

(1) IN GENERAL.—A group health plan, and a health insurance issuer that provides health insurance coverage, shall conduct utilization review activities in connection with the provision of benefits under such plan or coverage only in accordance with a utilization review program that meets the requirements of this section and section 102.

(2) USE OF OUTSIDE AGENTS.—Nothing in this section shall be construed as preventing a group health plan or health insurance issuer from arranging through a contract or otherwise for persons or entities to conduct utilization review activities on behalf of the plan or issuer, so long as such activities are conducted in accordance with a utilization review program that meets the requirements of this section.

(3) UTILIZATION REVIEW DEFINED.—For purposes of this section, the terms ''utilization review'' and ''utilization review activities'' mean procedures

used to monitor or evaluate the use or coverage, clinical necessity, appropriateness, efficacy, or efficiency of health care services, procedures or settings, and includes prospective review, concurrent review, second opinions, case management, discharge planning, or retrospective review.

(b) WRITTEN POLICIES AND CRITERIA.—

(1) WRITTEN POLICIES.—A utilization review program shall be conducted consistent with written policies and procedures that govern all aspects of the program.

(2) USE OF WRITTEN CRITERIA.—

(A) IN GENERAL.—Such a program shall utilize written clinical review criteria developed with input from a range of appropriate actively practicing health care professionals, as determined by the plan, pursuant to the program. Such criteria shall include written clinical review criteria that are based on valid clinical evidence where available and that are directed specifically at meeting the needs of at-risk populations and covered individuals with chronic conditions or severe illnesses, including gender-specific criteria and pediatric-specific criteria where available and appropriate.

(B) CONTINUING USE OF STANDARDS IN RETROSPECTIVE REVIEW.—If a health care service has been specifically pre-authorized or approved for a participant, beneficiary, or enrollee under such a program, the program shall not, pursuant to retrospective review, revise or modify the specific standards, criteria, or procedures used for the utilization review for procedures, treatment, and services delivered to the enrollee during the same course of treatment.

(C) REVIEW OF SAMPLE OF CLAIMS DENIALS.—Such a program shall provide for a periodic evaluation of the clinical appropriateness of at least a sample of denials of claims for benefits.

(c) CONDUCT OF PROGRAM ACTIVITIES.—

(1) ADMINISTRATION BY HEALTH CARE PROFESSIONALS.—A utilization review program shall be administered by qualified health care professionals who shall oversee review decisions.

(2) USE OF QUALIFIED, INDEPENDENT PERSONNEL.—

(A) IN GENERAL.—A utilization review program shall provide for the conduct of utilization review activities only through personnel

who are qualified and have received appropriate training in the conduct of such activities under the program.

(B) PROHIBITION OF CONTINGENT COMPENSATION ARRANGEMENTS.—Such a program shall not, with respect to utilization review activities, permit or provide compensation or anything of value to its employees, agents, or contractors in a manner that encourages denials of claims for benefits.

(C) PROHIBITION OF CONFLICTS.—Such a program shall not permit a health care professional who is providing health care services to an individual to perform utilization review activities in connection with the health care services being provided to the individual.

(3) ACCESSIBILITY OF REVIEW.—Such a program shall provide that appropriate personnel performing utilization review activities under the program, including the utilization review administrator, are reasonably accessible by toll-free telephone during normal business hours to discuss patient care and allow response to telephone requests, and that appropriate provision is made to receive and respond promptly to calls received during other hours.

(4) LIMITS ON FREQUENCY.—Such a program shall not provide for the performance of utilization review activities with respect to a class of services furnished to an individual more frequently than is reasonably required to assess whether the services under review are medically necessary or appropriate.

SEC. 102. PROCEDURES FOR INITIAL CLAIMS FOR BENEFITS AND PRIOR AUTHORIZATION DETERMINATIONS.

(a) PROCEDURES OF INITIAL CLAIMS FOR BENEFITS.—

(1) IN GENERAL.—A group health plan, or health insurance issuer offering health insurance coverage, shall—

(A) make a determination on an initial claim for benefits by a participant, beneficiary, or enrollee (or authorized representative) regarding payment or coverage for items or services under the terms and conditions of the plan or coverage involved, including any cost-sharing amount that the participant, beneficiary, or enrollee is required to pay with respect to such claim for benefits; and

(B) notify a participant, beneficiary, or enrollee (or authorized representative) and the

treating health care professional involved regarding a determination on an initial claim for benefits made under the terms and conditions of the plan or coverage, including any cost-sharing amounts that the participant, beneficiary, or enrollee may be required to make with respect to such claim for benefits, and of the right of the participant, beneficiary, or enrollee to an internal appeal under section 103.

(2) ACCESS TO INFORMATION.—

(A) TIMELY PROVISION OF NECESSARY INFORMATION.—With respect to an initial claim for benefits, the participant, beneficiary, or enrollee (or authorized representative) and the treating health care professional (if any) shall provide the plan or issuer with access to information requested by the plan or issuer that is necessary to make a determination relating to the claim. Such access shall be provided not later than 5 days after the date on which the request for information is received, or, in a case described in subparagraph (B) or (C) of subsection (b)(1), by such earlier time as may be necessary to comply with the applicable timeline under such subparagraph.

(B) LIMITED EFFECT OF FAILURE ON PLAN OR ISSUER'S OBLIGATIONS.—Failure of the participant, beneficiary, or enrollee to comply with the requirements of subparagraph (A) shall not remove the obligation of the plan or issuer to make a decision in accordance with the medical exigencies of the case and as soon as possible, based on the available information, and failure to comply with the time limit established by this paragraph shall not remove the obligation of the plan or issuer to comply with the requirements of this section.

(3) ORAL REQUESTS.—In the case of a claim for benefits involving an expedited or concurrent determination, a participant, beneficiary, or enrollee (or authorized representative) may make an initial claim for benefits orally, but a group health plan, or health insurance issuer offering health insurance coverage, may require that the participant, beneficiary, or enrollee (or authorized representative) provide written confirmation of such request in a timely manner on a form provided by the plan or issuer. In the case of such an oral request for benefits, the making of the request (and the timing of such request) shall be treated as the making at that

time of a claims for such benefits without regard to whether and when a written confirmation of such request is made.

(b) TIMELINE FOR MAKING DETERMINATIONS.—

(1) PRIOR AUTHORIZATION DETERMINATION.—

(A) IN GENERAL.—A group health plan, or health insurance issuer offering health insurance coverage, shall make a prior authorization determination on a claim for benefits (whether oral or written) in accordance with the medical exigencies of the case and as soon as possible, but in no case later than 14 days from the date on which the plan or issuer receives information that is reasonably necessary to enable the plan or issuer to make a determination on the request for prior authorization and in no case later than 28 days after the date of the claim for benefits is received.

(B) EXPEDITED DETERMINATION.—Notwithstanding subparagraph (A), a group health plan, or health insurance issuer offering health insurance coverage, shall expedite a prior authorization determination on a claim for benefits described in such subparagraph when a request for such an expedited determination is

made by a participant, beneficiary, or enrollee (or authorized representative) at any time during the process for making a determination and a health care professional certifies, with the request, that a determination under the procedures described in subparagraph (A) would seriously jeopardize the life or health of the participant, beneficiary, or enrollee or the ability of the participant, beneficiary, or enrollee to maintain or regain maximum function. Such determination shall be made in accordance with the medical exigencies of the case and as soon as possible, but in no case later than 72 hours after the time the request is received by the plan or issuer under this subparagraph.

(C) ONGOING CARE.—

(i) CONCURRENT REVIEW.—

(I) IN GENERAL.—Subject to clause (ii), in the case of a concurrent review of ongoing care (including hospitalization), which results in a termination or reduction of such care, the plan or issuer must provide by telephone and in printed form notice of the concurrent review determination

to the individual or the individual's designee and the individual's health care provider in accordance with the medical exigencies of the case and as soon as possible, with sufficient time prior to the termination or reduction to allow for an appeal under section 103(b)(3) to be completed before the termination or reduction takes effect.

(II) CONTENTS OF NOTICE.—Such notice shall include, with respect to ongoing health care items and services, the number of ongoing services approved, the new total of approved services, the date of onset of services, and the next review date, if any, as well as a statement of the individual's rights to further appeal.

(ii) RULE OF CONSTRUCTION.—Clause (i) shall not be construed as requiring plans or issuers to provide coverage of care that would exceed the coverage limitations for such care.

(2) RETROSPECTIVE DETERMINATION.—A group health plan, or health insurance issuer offer-

ing health insurance coverage, shall make a retrospective determination on a claim for benefits in accordance with the medical exigencies of the case and as soon as possible, but not later than 30 days after the date on which the plan or issuer receives information that is reasonably necessary to enable the plan or issuer to make a determination on the claim, or, if earlier, 60 days after the date of receipt of the claim for benefits.

(c) NOTICE OF A DENIAL OF A CLAIM FOR BENEFITS.—Written notice of a denial made under an initial claim for benefits shall be issued to the participant, beneficiary, or enrollee (or authorized representative) and the treating health care professional in accordance with the medical exigencies of the case and as soon as possible, but in no case later than 2 days after the date of the determination (or, in the case described in subparagraph (B) or (C) of subsection (b)(1), within the 72-hour or applicable period referred to in such subparagraph).

(d) REQUIREMENTS OF NOTICE OF DETERMINATIONS.—The written notice of a denial of a claim for benefits determination under subsection (c) shall be provided in printed form and written in a manner calculated to be understood by the average participant, beneficiary, or enrollee and shall include—

(1) the specific reasons for the determination (including a summary of the clinical or scientific evidence used in making the determination);

(2) the procedures for obtaining additional information concerning the determination; and

(3) notification of the right to appeal the determination and instructions on how to initiate an appeal in accordance with section 103.

(e) DEFINITIONS.—For purposes of this part:

(1) AUTHORIZED REPRESENTATIVE.—The term ''authorized representative'' means, with respect to an individual who is a participant, beneficiary, or enrollee, any health care professional or other person acting on behalf of the individual with the individual's consent or without such consent if the individual is medically unable to provide such consent.

(2) CLAIM FOR BENEFITS.—The term ''claim for benefits'' means any request for coverage (including authorization of coverage), for eligibility, or for payment in whole or in part, for an item or service under a group health plan or health insurance coverage.

(3) DENIAL OF CLAIM FOR BENEFITS.—The term ''denial'' means, with respect to a claim for benefits, a denial (in whole or in part) of, or a fail-

ure to act on a timely basis upon, the claim for benefits and includes a failure to provide benefits (including items and services) required to be provided under this title.

(4) TREATING HEALTH CARE PROFESSIONAL.—The term ''treating health care professional'' means, with respect to services to be provided to a participant, beneficiary, or enrollee, a health care professional who is primarily responsible for delivering those services to the participant, beneficiary, or enrollee.

SEC. 103. INTERNAL APPEALS OF CLAIMS DENIALS.

(a) RIGHT TO INTERNAL APPEAL.—

(1) IN GENERAL.—A participant, beneficiary, or enrollee (or authorized representative) may appeal any denial of a claim for benefits under section 102 under the procedures described in this section.

(2) TIME FOR APPEAL.—

(A) IN GENERAL.—A group health plan, or health insurance issuer offering health insurance coverage, shall ensure that a participant, beneficiary, or enrollee (or authorized representative) has a period of not less than 180 days beginning on the date of a denial of a claim for

benefits under section 102 in which to appeal such denial under this section.

(B) DATE OF DENIAL.—For purposes of subparagraph (A), the date of the denial shall be deemed to be the date as of which the participant, beneficiary, or enrollee knew of the denial of the claim for benefits.

(3) FAILURE TO ACT.—The failure of a plan or issuer to issue a determination on a claim for benefits under section 102 within the applicable timeline established for such a determination under such section is a denial of a claim for benefits for purposes this subtitle as of the date of the applicable deadline.

(4) PLAN WAIVER OF INTERNAL REVIEW.—A group health plan, or health insurance issuer offering health insurance coverage, may waive the internal review process under this section. In such case the plan or issuer shall provide notice to the participant, beneficiary, or enrollee (or authorized representative) involved, the participant, beneficiary, or enrollee (or authorized representative) involved shall be relieved of any obligation to complete the internal review involved, and may, at the option of such participant, beneficiary, enrollee, or representative pro-

ceed directly to seek further appeal through external review under section 104 or otherwise.

(b) TIMELINES FOR MAKING DETERMINATIONS.—

(1) ORAL REQUESTS.—In the case of an appeal of a denial of a claim for benefits under this section that involves an expedited or concurrent determination, a participant, beneficiary, or enrollee (or authorized representative) may request such appeal orally. A group health plan, or health insurance issuer offering health insurance coverage, may require that the participant, beneficiary, or enrollee (or authorized representative) provide written confirmation of such request in a timely manner on a form provided by the plan or issuer. In the case of such an oral request for an appeal of a denial, the making of the request (and the timing of such request) shall be treated as the making at that time of a request for an appeal without regard to whether and when a written confirmation of such request is made.

(2) ACCESS TO INFORMATION.—

(A) TIMELY PROVISION OF NECESSARY INFORMATION.—With respect to an appeal of a denial of a claim for benefits, the participant, beneficiary, or enrollee (or authorized represent-

ative) and the treating health care professional (if any) shall provide the plan or issuer with access to information requested by the plan or issuer that is necessary to make a determination relating to the appeal. Such access shall be provided not later than 5 days after the date on which the request for information is received, or, in a case described in subparagraph (B) or (C) of paragraph (3), by such earlier time as may be necessary to comply with the applicable timeline under such subparagraph.

(B) LIMITED EFFECT OF FAILURE ON PLAN OR ISSUER'S OBLIGATIONS.—Failure of the participant, beneficiary, or enrollee to comply with the requirements of subparagraph (A) shall not remove the obligation of the plan or issuer to make a decision in accordance with the medical exigencies of the case and as soon as possible, based on the available information, and failure to comply with the time limit established by this paragraph shall not remove the obligation of the plan or issuer to comply with the requirements of this section.

(3) PRIOR AUTHORIZATION DETERMINATIONS.—

(A) IN GENERAL.—A group health plan, or health insurance issuer offering health insurance coverage, shall make a determination on an appeal of a denial of a claim for benefits under this subsection in accordance with the medical exigencies of the case and as soon as possible, but in no case later than 14 days from the date on which the plan or issuer receives information that is reasonably necessary to enable the plan or issuer to make a determination on the appeal and in no case later than 28 days after the date the request for the appeal is received.

(B) EXPEDITED DETERMINATION.—Notwithstanding subparagraph (A), a group health plan, or health insurance issuer offering health insurance coverage, shall expedite a prior authorization determination on an appeal of a denial of a claim for benefits described in subparagraph (A), when a request for such an expedited determination is made by a participant, beneficiary, or enrollee (or authorized representative) at any time during the process for making a determination and a health care professional certifies, with the request, that a deter-

mination under the procedures described in subparagraph (A) would seriously jeopardize the life or health of the participant, beneficiary, or enrollee or the ability of the participant, beneficiary, or enrollee to maintain or regain maximum function. Such determination shall be made in accordance with the medical exigencies of the case and as soon as possible, but in no case later than 72 hours after the time the request for such appeal is received by the plan or issuer under this subparagraph.

(C) ONGOING CARE DETERMINATIONS.—

(i) IN GENERAL.—Subject to clause (ii), in the case of a concurrent review determination described in section 102(b)(1)(C)(i)(I), which results in a termination or reduction of such care, the plan or issuer must provide notice of the determination on the appeal under this section by telephone and in printed form to the individual or the individual's designee and the individual's health care provider in accordance with the medical exigencies of the case and as soon as possible, with sufficient time prior to the termination or re-

duction to allow for an external appeal under section 104 to be completed before the termination or reduction takes effect.

(ii) RULE OF CONSTRUCTION.—Clause (i) shall not be construed as requiring plans or issuers to provide coverage of care that would exceed the coverage limitations for such care.

(4) RETROSPECTIVE DETERMINATION.—A group health plan, or health insurance issuer offering health insurance coverage, shall make a retrospective determination on an appeal of a claim for benefits in no case later than 30 days after the date on which the plan or issuer receives necessary information that is reasonably necessary to enable the plan or issuer to make a determination on the appeal and in no case later than 60 days after the date the request for the appeal is received.

(c) CONDUCT OF REVIEW.—

(1) IN GENERAL.—A review of a denial of a claim for benefits under this section shall be conducted by an individual with appropriate expertise who was not involved in the initial determination.

(2) REVIEW OF MEDICAL DECISIONS BY PHYSICIANS.—A review of an appeal of a denial of a claim

for benefits that is based on a lack of medical necessity and appropriateness, or based on an experimental or investigational treatment, or requires an evaluation of medical facts, shall be made by a physician (allopathic or osteopathic) with appropriate expertise (including, in the case of a child, appropriate pediatric expertise) who was not involved in the initial determination.

(d) NOTICE OF DETERMINATION.—

(1) IN GENERAL.—Written notice of a determination made under an internal appeal of a denial of a claim for benefits shall be issued to the participant, beneficiary, or enrollee (or authorized representative) and the treating health care professional in accordance with the medical exigencies of the case and as soon as possible, but in no case later than 2 days after the date of completion of the review (or, in the case described in subparagraph (B) or (C) of subsection (b)(3), within the 72-hour or applicable period referred to in such subparagraph).

(2) FINAL DETERMINATION.—The decision by a plan or issuer under this section shall be treated as the final determination of the plan or issuer on a denial of a claim for benefits. The failure of a plan or issuer to issue a determination on an appeal of a de-

nial of a claim for benefits under this section within the applicable timeline established for such a determination shall be treated as a final determination on an appeal of a denial of a claim for benefits for purposes of proceeding to external review under section 104.

(3) REQUIREMENTS OF NOTICE.—With respect to a determination made under this section, the notice described in paragraph (1) shall be provided in printed form and written in a manner calculated to be understood by the average participant, beneficiary, or enrollee and shall include—

(A) the specific reasons for the determination (including a summary of the clinical or scientific evidence used in making the determination);

(B) the procedures for obtaining additional information concerning the determination; and

(C) notification of the right to an independent external review under section 104 and instructions on how to initiate such a review.

SEC. 104. INDEPENDENT EXTERNAL APPEALS PROCEDURES.

(a) RIGHT TO EXTERNAL APPEAL.—A group health plan, and a health insurance issuer offering health insur-

ance coverage, shall provide in accordance with this section participants, beneficiaries, and enrollees (or authorized representatives) with access to an independent external review for any denial of a claim for benefits.

(b) INITIATION OF THE INDEPENDENT EXTERNAL REVIEW PROCESS.—

(1) TIME TO FILE.—A request for an independent external review under this section shall be filed with the plan or issuer not later than 180 days after the date on which the participant, beneficiary, or enrollee receives notice of the denial under section 103(d) or notice of waiver of internal review under section 103(a)(4) or the date on which the plan or issuer has failed to make a timely decision under section 103(d)(2) and notifies the participant or beneficiary that it has failed to make a timely decision and that the beneficiary must file an appeal with an external review entity within 180 days if the participant or beneficiary desires to file such an appeal.

(2) FILING OF REQUEST.—

(A) IN GENERAL.—Subject to the succeeding provisions of this subsection, a group health plan, and a health insurance issuer offering health insurance coverage, may—

(i) except as provided in subparagraph (B)(i), require that a request for review be in writing;

(ii) limit the filing of such a request to the participant, beneficiary, or enrollee involved (or an authorized representative);

(iii) except if waived by the plan or issuer under section 103(a)(4), condition access to an independent external review under this section upon a final determination of a denial of a claim for benefits under the internal review procedure under section 103;

(iv) except as provided in subparagraph (B)(ii), require payment of a filing fee to the plan or issuer of a sum that does not exceed $25; and

(v) require that a request for review include the consent of the participant, beneficiary, or enrollee (or authorized representative) for the release of necessary medical information or records of the participant, beneficiary, or enrollee to the qualified external review entity only for

purposes of conducting external review activities.

(B) REQUIREMENTS AND EXCEPTION RELATING TO GENERAL RULE.—

(i) ORAL REQUESTS PERMITTED IN EXPEDITED OR CONCURRENT CASES.—In the case of an expedited or concurrent external review as provided for under subsection (e), the request may be made orally. A group health plan, or health insurance issuer offering health insurance coverage, may require that the participant, beneficiary, or enrollee (or authorized representative) provide written confirmation of such request in a timely manner on a form provided by the plan or issuer. Such written confirmation shall be treated as a consent for purposes of subparagraph (A)(v). In the case of such an oral request for such a review, the making of the request (and the timing of such request) shall be treated as the making at that time of a request for such an external review without regard to whether and when a

written confirmation of such request is made.

(ii) EXCEPTION TO FILING FEE REQUIREMENT.—

(I) INDIGENCY.—Payment of a filing fee shall not be required under subparagraph (A)(iv) where there is a certification (in a form and manner specified in guidelines established by the appropriate Secretary) that the participant, beneficiary, or enrollee is indigent (as defined in such guidelines).

(II) FEE NOT REQUIRED.—Payment of a filing fee shall not be required under subparagraph (A)(iv) if the plan or issuer waives the internal appeals process under section 103(a)(4).

(III) REFUNDING OF FEE.—The filing fee paid under subparagraph (A)(iv) shall be refunded if the determination under the independent external review is to reverse or modify the

denial which is the subject of the review.

(IV) COLLECTION OF FILING FEE.—The failure to pay such a filing fee shall not prevent the consideration of a request for review but, subject to the preceding provisions of this clause, shall constitute a legal liability to pay.

(c) REFERRAL TO QUALIFIED EXTERNAL REVIEW ENTITY UPON REQUEST.—

(1) IN GENERAL.—Upon the filing of a request for independent external review with the group health plan, or health insurance issuer offering health insurance coverage, the plan or issuer shall immediately refer such request, and forward the plan or issuer's initial decision (including the information described in section 103(d)(3)(A)), to a qualified external review entity selected in accordance with this section.

(2) ACCESS TO PLAN OR ISSUER AND HEALTH PROFESSIONAL INFORMATION.—With respect to an independent external review conducted under this section, the participant, beneficiary, or enrollee (or authorized representative), the plan or issuer, and the treating health care professional (if any) shall

provide the external review entity with information that is necessary to conduct a review under this section, as determined and requested by the entity. Such information shall be provided not later than 5 days after the date on which the request for information is received, or, in a case described in clause (ii) or (iii) of subsection (e)(1)(A), by such earlier time as may be necessary to comply with the applicable timeline under such clause.

(3) SCREENING OF REQUESTS BY QUALIFIED EXTERNAL REVIEW ENTITIES.—

(A) IN GENERAL.—With respect to a request referred to a qualified external review entity under paragraph (1) relating to a denial of a claim for benefits, the entity shall refer such request for the conduct of an independent medical review unless the entity determines that—

(i) any of the conditions described in clauses (ii) or (iii) of subsection (b)(2)(A) have not been met;

(ii) the denial of the claim for benefits does not involve a medically reviewable decision under subsection (d)(2);

(iii) the denial of the claim for benefits relates to a decision regarding whether

an individual is a participant, beneficiary, or enrollee who is enrolled under the terms and conditions of the plan or coverage (including the applicability of any waiting period under the plan or coverage); or

(iv) the denial of the claim for benefits is a decision as to the application of cost-sharing requirements or the application of a specific exclusion or express limitation on the amount, duration, or scope of coverage of items or services under the terms and conditions of the plan or coverage unless the decision is a denial described in subsection (d)(2).

Upon making a determination that any of clauses (i) through (iv) applies with respect to the request, the entity shall determine that the denial of a claim for benefits involved is not eligible for independent medical review under subsection (d), and shall provide notice in accordance with subparagraph (C).

(B) PROCESS FOR MAKING DETERMINATIONS.—

(i) NO DEFERENCE TO PRIOR DETERMINATIONS.—In making determinations

under subparagraph (A), there shall be no deference given to determinations made by the plan or issuer or the recommendation of a treating health care professional (if any).

(ii) USE OF APPROPRIATE PERSONNEL.—A qualified external review entity shall use appropriately qualified personnel to make determinations under this section.

(C) NOTICES AND GENERAL TIMELINES FOR DETERMINATION.—

(i) NOTICE IN CASE OF DENIAL OF REFERRAL.—If the entity under this paragraph does not make a referral to an independent medical reviewer, the entity shall provide notice to the plan or issuer, the participant, beneficiary, or enrollee (or authorized representative) filing the request, and the treating health care professional (if any) that the denial is not subject to independent medical review. Such notice—

(I) shall be written (and, in addition, may be provided orally) in a

manner calculated to be understood by an average participant or enrollee;

(II) shall include the reasons for the determination;

(III) include any relevant terms and conditions of the plan or coverage; and

(IV) include a description of any further recourse available to the individual.

(ii) GENERAL TIMELINE FOR DETERMINATIONS.—Upon receipt of information under paragraph (2), the qualified external review entity, and if required the independent medical reviewer, shall make a determination within the overall timeline that is applicable to the case under review as described in subsection (e), except that if the entity determines that a referral to an independent medical reviewer is not required, the entity shall provide notice of such determination to the participant, beneficiary, or enrollee (or authorized representative) within such timeline and with-

in 2 days of the date of such determination.

(d) INDEPENDENT MEDICAL REVIEW.—

(1) IN GENERAL.—If a qualified external review entity determines under subsection (c) that a denial of a claim for benefits is eligible for independent medical review, the entity shall refer the denial involved to an independent medical reviewer for the conduct of an independent medical review under this subsection.

(2) MEDICALLY REVIEWABLE DECISIONS.—A denial of a claim for benefits is eligible for independent medical review if the benefit for the item or service for which the claim is made would be a covered benefit under the terms and conditions of the plan or coverage but for one (or more) of the following determinations:

(A) DENIALS BASED ON MEDICAL NECESSITY AND APPROPRIATENESS.—A determination that the item or service is not covered because it is not medically necessary and appropriate or based on the application of substantially equivalent terms.

(B) DENIALS BASED ON EXPERIMENTAL OR INVESTIGATIONAL TREATMENT.—A deter-

mination that the item or service is not covered because it is experimental or investigational or based on the application of substantially equivalent terms.

(C) DENIALS OTHERWISE BASED ON AN EVALUATION OF MEDICAL FACTS.—A determination that the item or service or condition is not covered based on grounds that require an evaluation of the medical facts by a health care professional in the specific case involved to determine the coverage and extent of coverage of the item or service or condition.

(3) INDEPENDENT MEDICAL REVIEW DETERMINATION.—

(A) IN GENERAL.—An independent medical reviewer under this section shall make a new independent determination with respect to whether or not the denial of a claim for a benefit that is the subject of the review should be upheld, reversed, or modified.

(B) STANDARD FOR DETERMINATION.—The independent medical reviewer's determination relating to the medical necessity and appropriateness, or the experimental or investigation nature, or the evaluation of the medical

facts of the item, service, or condition shall be based on the medical condition of the participant, beneficiary, or enrollee (including the medical records of the participant, beneficiary, or enrollee) and valid, relevant scientific evidence and clinical evidence, including peer-reviewed medical literature or findings and including expert opinion.

(C) NO COVERAGE FOR EXCLUDED BENEFITS.—Nothing in this subsection shall be construed to permit an independent medical reviewer to require that a group health plan, or health insurance issuer offering health insurance coverage, provide coverage for items or services for which benefits are specifically excluded or expressly limited under the plan or coverage in the plain language of the plan document (and which are disclosed under section 121(b)(1)(C)) except to the extent that the application or interpretation of the exclusion or limitation involves a determination described in paragraph (2).

(D) EVIDENCE AND INFORMATION TO BE USED IN MEDICAL REVIEWS.—In making a determination under this subsection, the inde-

pendent medical reviewer shall also consider appropriate and available evidence and information, including the following:

(i) The determination made by the plan or issuer with respect to the claim upon internal review and the evidence, guidelines, or rationale used by the plan or issuer in reaching such determination.

(ii) The recommendation of the treating health care professional and the evidence, guidelines, and rationale used by the treating health care professional in reaching such recommendation.

(iii) Additional relevant evidence or information obtained by the reviewer or submitted by the plan, issuer, participant, beneficiary, or enrollee (or an authorized representative), or treating health care professional.

(iv) The plan or coverage document.

(E) INDEPENDENT DETERMINATION.—In making determinations under this subtitle, a qualified external review entity and an independent medical reviewer shall—

(i) consider the claim under review without deference to the determinations made by the plan or issuer or the recommendation of the treating health care professional (if any); and

(ii) consider, but not be bound by the definition used by the plan or issuer of ''medically necessary and appropriate'', or ''experimental or investigational'', or other substantially equivalent terms that are used by the plan or issuer to describe medical necessity and appropriateness or experimental or investigational nature of the treatment.

(F) DETERMINATION OF INDEPENDENT MEDICAL REVIEWER.—An independent medical reviewer shall, in accordance with the deadlines described in subsection (e), prepare a written determination to uphold, reverse, or modify the denial under review. Such written determination shall include—

(i) the determination of the reviewer;

(ii) the specific reasons of the reviewer for such determination, including a summary of the clinical or scientific evi-

dence used in making the determination; and

(iii) with respect to a determination to reverse or modify the denial under review, a timeframe within which the plan or issuer must comply with such determination.

(G) NONBINDING NATURE OF ADDITIONAL RECOMMENDATIONS.—In addition to the determination under subparagraph (F), the reviewer may provide the plan or issuer and the treating health care professional with additional recommendations in connection with such a determination, but any such recommendations shall not affect (or be treated as part of) the determination and shall not be binding on the plan or issuer.

(e) TIMELINES AND NOTIFICATIONS.—

(1) TIMELINES FOR INDEPENDENT MEDICAL REVIEW.—

(A) PRIOR AUTHORIZATION DETERMINATION.—

(i) IN GENERAL.—The independent medical reviewer (or reviewers) shall make a determination on a denial of a claim for

benefits that is referred to the reviewer under subsection (c)(3) in accordance with the medical exigencies of the case and as soon as possible, but in no case later than 14 days after the date of receipt of information under subsection (c)(2) if the review involves a prior authorization of items or services and in no case later than 21 days after the date the request for external review is received.

(ii) EXPEDITED DETERMINATION.—Notwithstanding clause (i) and subject to clause (iii), the independent medical reviewer (or reviewers) shall make an expedited determination on a denial of a claim for benefits described in clause (i), when a request for such an expedited determination is made by a participant, beneficiary, or enrollee (or authorized representative) at any time during the process for making a determination, and a health care professional certifies, with the request, that a determination under the timeline described in clause (i) would seriously jeopardize the life or health of the participant, bene-

ficiary, or enrollee or the ability of the participant, beneficiary, or enrollee to maintain or regain maximum function. Such determination shall be made as soon in accordance with the medical exigencies of the case and as soon as possible, but in no case later than 72 hours after the time the request for external review is received by the qualified external review entity.

(iii) ONGOING CARE DETERMINATION.—Notwithstanding clause (i), in the case of a review described in such subclause that involves a termination or reduction of care, the notice of the determination shall be completed not later than 24 hours after the time the request for external review is received by the qualified external review entity and before the end of the approved period of care.

(B) RETROSPECTIVE DETERMINATION.—The independent medical reviewer (or reviewers) shall complete a review in the case of a retrospective determination on an appeal of a denial of a claim for benefits that is referred to the reviewer under subsection (c)(3) in no case

later than 30 days after the date of receipt of information under subsection (c)(2) and in no case later than 60 days after the date the request for external review is received by the qualified external review entity.

(2) NOTIFICATION OF DETERMINATION.—The external review entity shall ensure that the plan or issuer, the participant, beneficiary, or enrollee (or authorized representative) and the treating health care professional (if any) receives a copy of the written determination of the independent medical reviewer prepared under subsection (d)(3)(F). Nothing in this paragraph shall be construed as preventing an entity or reviewer from providing an initial oral notice of the reviewer's determination.

(3) FORM OF NOTICES.—Determinations and notices under this subsection shall be written in a manner calculated to be understood by an average participant.

(f) COMPLIANCE.—

(1) APPLICATION OF DETERMINATIONS.—

(A) EXTERNAL REVIEW DETERMINATIONS BINDING ON PLAN.—The determinations of an external review entity and an independent med-

ical reviewer under this section shall be binding upon the plan or issuer involved.

(B) COMPLIANCE WITH DETERMINATION.—If the determination of an independent medical reviewer is to reverse or modify the denial, the plan or issuer, upon the receipt of such determination, shall authorize coverage to comply with the medical reviewer's determination in accordance with the timeframe established by the medical reviewer.

(2) FAILURE TO COMPLY.—

(A) IN GENERAL.—If a plan or issuer fails to comply with the timeframe established under paragraph (1)(B) with respect to a participant, beneficiary, or enrollee, where such failure to comply is caused by the plan or issuer, the participant, beneficiary, or enrollee may obtain the items or services involved (in a manner consistent with the determination of the independent external reviewer) from any provider regardless of whether such provider is a participating provider under the plan or coverage.

(B) REIMBURSEMENT.—

(i) IN GENERAL.—Where a participant, beneficiary, or enrollee obtains items

or services in accordance with subparagraph (A), the plan or issuer involved shall provide for reimbursement of the costs of such items or services. Such reimbursement shall be made to the treating health care professional or to the participant, beneficiary, or enrollee (in the case of a participant, beneficiary, or enrollee who pays for the costs of such items or services).

(ii) AMOUNT.—The plan or issuer shall fully reimburse a professional, participant, beneficiary, or enrollee under clause (i) for the total costs of the items or services provided (regardless of any plan limitations that may apply to the coverage of such items or services) so long as the items or services were provided in a manner consistent with the determination of the independent medical reviewer.

(C) FAILURE TO REIMBURSE.—Where a plan or issuer fails to provide reimbursement to a professional, participant, beneficiary, or enrollee in accordance with this paragraph, the professional, participant, beneficiary, or enrollee may commence a civil action (or utilize other

remedies available under law) to recover only the amount of any such reimbursement that is owed by the plan or issuer and any necessary legal costs or expenses (including attorney's fees) incurred in recovering such reimbursement.

(D) AVAILABLE REMEDIES.—The remedies provided under this paragraph are in addition to any other available remedies.

(3) PENALTIES AGAINST AUTHORIZED OFFICIALS FOR REFUSING TO AUTHORIZE THE DETERMINATION OF AN EXTERNAL REVIEW ENTITY.—

(A) MONETARY PENALTIES.—

(i) IN GENERAL.—In any case in which the determination of an external review entity is not followed by a group health plan, or by a health insurance issuer offering health insurance coverage, any person who, acting in the capacity of authorizing the benefit, causes such refusal may, in the discretion in a court of competent jurisdiction, be liable to an aggrieved participant, beneficiary, or enrollee for a civil penalty in an amount of up to $1,000 a day from the date on which the

determination was transmitted to the plan or issuer by the external review entity until the date the refusal to provide the benefit is corrected.

(ii) ADDITIONAL PENALTY FOR FAILING TO FOLLOW TIMELINE.—In any case in which treatment was not commenced by the plan in accordance with the determination of an independent external reviewer, the Secretary shall assess a civil penalty of $10,000 against the plan and the plan shall pay such penalty to the participant, beneficiary, or enrollee involved.

(B) CEASE AND DESIST ORDER AND ORDER OF ATTORNEY'S FEES.—In any action described in subparagraph (A) brought by a participant, beneficiary, or enrollee with respect to a group health plan, or a health insurance issuer offering health insurance coverage, in which a plaintiff alleges that a person referred to in such subparagraph has taken an action resulting in a refusal of a benefit determined by an external appeal entity to be covered, or has failed to take an action for which such person is responsible under the terms and conditions of

the plan or coverage and which is necessary under the plan or coverage for authorizing a benefit, the court shall cause to be served on the defendant an order requiring the defendant—

(i) to cease and desist from the alleged action or failure to act; and

(ii) to pay to the plaintiff a reasonable attorney's fee and other reasonable costs relating to the prosecution of the action on the charges on which the plaintiff prevails.

(C) ADDITIONAL CIVIL PENALTIES.—

(i) IN GENERAL.—In addition to any penalty imposed under subparagraph (A) or (B), the appropriate Secretary may assess a civil penalty against a person acting in the capacity of authorizing a benefit determined by an external review entity for one or more group health plans, or health insurance issuers offering health insurance coverage, for—

(I) any pattern or practice of repeated refusal to authorize a benefit determined by an external appeal entity to be covered; or

(II) any pattern or practice of repeated violations of the requirements of this section with respect to such plan or coverage.

(ii) STANDARD OF PROOF AND AMOUNT OF PENALTY.—Such penalty shall be payable only upon proof by clear and convincing evidence of such pattern or practice and shall be in an amount not to exceed the lesser of—

(I) 25 percent of the aggregate value of benefits shown by the appropriate Secretary to have not been provided, or unlawfully delayed, in violation of this section under such pattern or practice; or

(II) $500,000.

(D) REMOVAL AND DISQUALIFICATION.—Any person acting in the capacity of authorizing benefits who has engaged in any such pattern or practice described in subparagraph (C)(i) with respect to a plan or coverage, upon the petition of the appropriate Secretary, may be removed by the court from such position, and from any other involvement, with respect to

such a plan or coverage, and may be precluded from returning to any such position or involvement for a period determined by the court.

(4) PROTECTION OF LEGAL RIGHTS.—Nothing in this subsection or subtitle shall be construed as altering or eliminating any cause of action or legal rights or remedies of participants, beneficiaries, enrollees, and others under State or Federal law (including sections 502 and 503 of the Employee Retirement Income Security Act of 1974), including the right to file judicial actions to enforce rights.

(g) QUALIFICATIONS OF INDEPENDENT MEDICAL REVIEWERS.—

(1) IN GENERAL.—In referring a denial to 1 or more individuals to conduct independent medical review under subsection (c), the qualified external review entity shall ensure that—

(A) each independent medical reviewer meets the qualifications described in paragraphs (2) and (3);

(B) with respect to each review at least 1 such reviewer meets the requirements described in paragraphs (4) and (5); and

(C) compensation provided by the entity to the reviewer is consistent with paragraph (6).

(2) LICENSURE AND EXPERTISE.—Each independent medical reviewer shall be a physician (allopathic or osteopathic) or health care professional who—

(A) is appropriately credentialed or licensed in 1 or more States to deliver health care services; and

(B) typically treats the condition, makes the diagnosis, or provides the type of treatment under review.

(3) INDEPENDENCE.—

(A) IN GENERAL.—Subject to subparagraph (B), each independent medical reviewer in a case shall—

(i) not be a related party (as defined in paragraph (7));

(ii) not have a material familial, financial, or professional relationship with such a party; and

(iii) not otherwise have a conflict of interest with such a party (as determined under regulations).

(B) EXCEPTION.—Nothing in subparagraph (A) shall be construed to—

(i) prohibit an individual, solely on the basis of affiliation with the plan or issuer, from serving as an independent medical reviewer if—

(I) a non-affiliated individual is not reasonably available;

(II) the affiliated individual is not involved in the provision of items or services in the case under review;

(III) the fact of such an affiliation is disclosed to the plan or issuer and the participant, beneficiary, or enrollee (or authorized representative) and neither party objects; and

(IV) the affiliated individual is not an employee of the plan or issuer and does not provide services exclusively or primarily to or on behalf of the plan or issuer;

(ii) prohibit an individual who has staff privileges at the institution where the treatment involved takes place from serving as an independent medical reviewer merely on the basis of such affiliation if the affiliation is disclosed to the plan or

issuer and the participant, beneficiary, or enrollee (or authorized representative), and neither party objects; or

(iii) prohibit receipt of compensation by an independent medical reviewer from an entity if the compensation is provided consistent with paragraph (6).

(4) PRACTICING HEALTH CARE PROFESSIONAL IN SAME FIELD.—

(A) IN GENERAL.—In a case involving treatment, or the provision of items or services—

(i) by a physician, a reviewer shall be a practicing physician (allopathic or osteopathic) of the same or similar specialty, as a physician who typically treats the condition, makes the diagnosis, or provides the type of treatment under review; or

(ii) by a health care professional (other than a physician), a reviewer shall be a practicing physician (allopathic or osteopathic) or, if determined appropriate by the qualified external review entity, a practicing health care professional (other than such a physician), of the same or similar

specialty as the health care professional who typically treats the condition, makes the diagnosis, or provides the type of treatment under review.

(B) PRACTICING DEFINED.—For purposes of this paragraph, the term ''practicing'' means, with respect to an individual who is a physician or other health care professional that the individual provides health care services to individual patients on average at least 2 days per week.

(5) PEDIATRIC EXPERTISE.—In the case of an external review relating to a child, a reviewer shall have expertise under paragraph (2) in pediatrics.

(6) LIMITATIONS ON REVIEWER COMPENSATION.—Compensation provided by a qualified external review entity to an independent medical reviewer in connection with a review under this section shall—

(A) not exceed a reasonable level; and

(B) not be contingent on the decision rendered by the reviewer.

(7) RELATED PARTY DEFINED.—For purposes of this section, the term ''related party'' means, with respect to a denial of a claim under a plan or cov-

erage relating to a participant, beneficiary, or enrollee, any of the following:

(A) The plan, plan sponsor, or issuer involved, or any fiduciary, officer, director, or employee of such plan, plan sponsor, or issuer.

(B) The participant, beneficiary, or enrollee (or authorized representative).

(C) The health care professional that provides the items or services involved in the denial.

(D) The institution at which the items or services (or treatment) involved in the denial are provided.

(E) The manufacturer of any drug or other item that is included in the items or services involved in the denial.

(F) Any other party determined under any regulations to have a substantial interest in the denial involved.

(h) QUALIFIED EXTERNAL REVIEW ENTITIES.—

(1) SELECTION OF QUALIFIED EXTERNAL REVIEW ENTITIES.—

(A) LIMITATION ON PLAN OR ISSUER SELECTION.—The appropriate Secretary shall implement procedures—

(i) to assure that the selection process among qualified external review entities will not create any incentives for external review entities to make a decision in a biased manner; and

(ii) for auditing a sample of decisions by such entities to assure that no such decisions are made in a biased manner.

No such selection process under the procedures implemented by the appropriate Secretary may give either the patient or the plan or issuer any ability to determine or influence the selection of a qualified external review entity to review the case of any participant, beneficiary, or enrollee.

(B) STATE AUTHORITY WITH RESPECT TO QUALIFIED EXTERNAL REVIEW ENTITIES FOR HEALTH INSURANCE ISSUERS.—With respect to health insurance issuers offering health insurance coverage in a State, the State may provide for external review activities to be conducted by a qualified external appeal entity that is designated by the State or that is selected by the State in a manner determined by the State to assure an unbiased determination.

(2) CONTRACT WITH QUALIFIED EXTERNAL REVIEW ENTITY.—Except as provided in paragraph (1)(B), the external review process of a plan or issuer under this section shall be conducted under a contract between the plan or issuer and 1 or more qualified external review entities (as defined in paragraph (4)(A)).

(3) TERMS AND CONDITIONS OF CONTRACT.—The terms and conditions of a contract under paragraph (2) shall—

(A) be consistent with the standards the appropriate Secretary shall establish to assure there is no real or apparent conflict of interest in the conduct of external review activities; and

(B) provide that the costs of the external review process shall be borne by the plan or issuer.

Subparagraph (B) shall not be construed as applying to the imposition of a filing fee under subsection (b)(2)(A)(iv) or costs incurred by the participant, beneficiary, or enrollee (or authorized representative) or treating health care professional (if any) in support of the review, including the provision of additional evidence or information.

(4) QUALIFICATIONS.—

(A) IN GENERAL.—In this section, the term ''qualified external review entity'' means, in relation to a plan or issuer, an entity that is initially certified (and periodically recertified) under subparagraph (C) as meeting the following requirements:

(i) The entity has (directly or through contracts or other arrangements) sufficient medical, legal, and other expertise and sufficient staffing to carry out duties of a qualified external review entity under this section on a timely basis, including making determinations under subsection (b)(2)(A) and providing for independent medical reviews under subsection (d).

(ii) The entity is not a plan or issuer or an affiliate or a subsidiary of a plan or issuer, and is not an affiliate or subsidiary of a professional or trade association of plans or issuers or of health care providers.

(iii) The entity has provided assurances that it will conduct external review activities consistent with the applicable requirements of this section and standards specified in subparagraph (C), including

that it will not conduct any external review activities in a case unless the independence requirements of subparagraph (B) are met with respect to the case.

(iv) The entity has provided assurances that it will provide information in a timely manner under subparagraph (D).

(v) The entity meets such other requirements as the appropriate Secretary provides by regulation.

(B) INDEPENDENCE REQUIREMENTS.—

(i) IN GENERAL.—Subject to clause (ii), an entity meets the independence requirements of this subparagraph with respect to any case if the entity—

(I) is not a related party (as defined in subsection (g)(7));

(II) does not have a material familial, financial, or professional relationship with such a party; and

(III) does not otherwise have a conflict of interest with such a party (as determined under regulations).

(ii) EXCEPTION FOR REASONABLE COMPENSATION.—Nothing in clause (i)

shall be construed to prohibit receipt by a qualified external review entity of compensation from a plan or issuer for the conduct of external review activities under this section if the compensation is provided consistent with clause (iii).

(iii) LIMITATIONS ON ENTITY COMPENSATION.—Compensation provided by a plan or issuer to a qualified external review entity in connection with reviews under this section shall—

(I) not exceed a reasonable level; and

(II) not be contingent on any decision rendered by the entity or by any independent medical reviewer.

(C) CERTIFICATION AND RECERTIFICATION PROCESS.—

(i) IN GENERAL.—The initial certification and recertification of a qualified external review entity shall be made—

(I) under a process that is recognized or approved by the appropriate Secretary; or

(II) by a qualified private standard-setting organization that is approved by the appropriate Secretary under clause (iii).

In taking action under subclause (I), the appropriate Secretary shall give deference to entities that are under contract with the Federal Government or with an applicable State authority to perform functions of the type performed by qualified external review entities.

(ii) PROCESS.—The appropriate Secretary shall not recognize or approve a process under clause (i)(I) unless the process applies standards (as promulgated in regulations) that ensure that a qualified external review entity—

(I) will carry out (and has carried out, in the case of recertification) the responsibilities of such an entity in accordance with this section, including meeting applicable deadlines;

(II) will meet (and has met, in the case of recertification) appropriate indicators of fiscal integrity;

(III) will maintain (and has maintained, in the case of recertification) appropriate confidentiality with respect to individually identifiable health information obtained in the course of conducting external review activities; and

(IV) in the case of recertification, shall review the matters described in clause (iv).

(iii) APPROVAL OF QUALIFIED PRIVATE STANDARD-SETTING ORGANIZATIONS.—For purposes of clause (i)(II), the appropriate Secretary may approve a qualified private standard-setting organization if such Secretary finds that the organization only certifies (or recertifies) external review entities that meet at least the standards required for the certification (or recertification) of external review entities under clause (ii).

(iv) CONSIDERATIONS IN RECERTIFICATIONS.—In conducting recertifications of a qualified external review entity under this paragraph, the appropriate Secretary

or organization conducting the recertification shall review compliance of the entity with the requirements for conducting external review activities under this section, including the following:

(I) Provision of information under subparagraph (D).

(II) Adherence to applicable deadlines (both by the entity and by independent medical reviewers it refers cases to).

(III) Compliance with limitations on compensation (with respect to both the entity and independent medical reviewers it refers cases to).

(IV) Compliance with applicable independence requirements.

(v) PERIOD OF CERTIFICATION OR RECERTIFICATION.—A certification or recertification provided under this paragraph shall extend for a period not to exceed 2 years.

(vi) REVOCATION.—A certification or recertification under this paragraph may be revoked by the appropriate Secretary or

by the organization providing such certification upon a showing of cause.

(vii) SUFFICIENT NUMBER OF ENTITIES.—The appropriate Secretary shall certify and recertify a number of external review entities which is sufficient to ensure the timely and efficient provision of review services.

(D) PROVISION OF INFORMATION.—

(i) IN GENERAL.—A qualified external review entity shall provide to the appropriate Secretary, in such manner and at such times as such Secretary may require, such information (relating to the denials which have been referred to the entity for the conduct of external review under this section) as such Secretary determines appropriate to assure compliance with the independence and other requirements of this section to monitor and assess the quality of its external review activities and lack of bias in making determinations. Such information shall include information described in clause (ii) but shall not include

individually identifiable medical information.

(ii) INFORMATION TO BE INCLUDED.—The information described in this subclause with respect to an entity is as follows:

(I) The number and types of denials for which a request for review has been received by the entity.

(II) The disposition by the entity of such denials, including the number referred to a independent medical reviewer and the reasons for such dispositions (including the application of exclusions), on a plan or issuer-specific basis and on a health care specialty-specific basis.

(III) The length of time in making determinations with respect to such denials.

(IV) Updated information on the information required to be submitted as a condition of certification with respect to the entity's performance of external review activities.

(iii) INFORMATION TO BE PROVIDED TO CERTIFYING ORGANIZATION.—

(I) IN GENERAL.—In the case of a qualified external review entity which is certified (or recertified) under this subsection by a qualified private standard-setting organization, at the request of the organization, the entity shall provide the organization with the information provided to the appropriate Secretary under clause (i).

(II) ADDITIONAL INFORMATION.—Nothing in this subparagraph shall be construed as preventing such an organization from requiring additional information as a condition of certification or recertification of an entity.

(iv) USE OF INFORMATION.—Information provided under this subparagraph may be used by the appropriate Secretary and qualified private standard-setting organizations to conduct oversight of qualified external review entities, including recertifi-

cation of such entities, and shall be made available to the public in an appropriate manner.

(E) LIMITATION ON LIABILITY.—No qualified external review entity having a contract with a plan or issuer, and no person who is employed by any such entity or who furnishes professional services to such entity (including as an independent medical reviewer), shall be held by reason of the performance of any duty, function, or activity required or authorized pursuant to this section, to be civilly liable under any law of the United States or of any State (or political subdivision thereof) if there was no actual malice or gross misconduct in the performance of such duty, function, or activity.

Subtitle B—Access to Care

SEC. 111. CONSUMER CHOICE OPTION.

(a) IN GENERAL.—If—

(1) a health insurance issuer providing health insurance coverage in connection with a group health plan offers to enrollees health insurance coverage which provides for coverage of services only if such services are furnished through health care professionals and providers who are members of a network

of health care professionals and providers who have entered into a contract with the issuer to provide such services, or

(2) a group health plan offers to participants or beneficiaries health benefits which provide for coverage of services only if such services are furnished through health care professionals and providers who are members of a network of health care professionals and providers who have entered into a contract with the plan to provide such services,

then the issuer or plan shall also offer or arrange to be offered to such enrollees, participants, or beneficiaries (at the time of enrollment and during an annual open season as provided under subsection (c)) the option of health insurance coverage or health benefits which provide for coverage of such services which are not furnished through health care professionals and providers who are members of such a network unless such enrollees, participants, or beneficiaries are offered such non-network coverage through another group health plan or through another health insurance issuer in the group market.

(b) ADDITIONAL COSTS.—The amount of any additional premium charged by the health insurance issuer or group health plan for the additional cost of the creation and maintenance of the option described in subsection (a)

and the amount of any additional cost sharing imposed under such option shall be borne by the enrollee, participant, or beneficiary unless it is paid by the health plan sponsor or group health plan through agreement with the health insurance issuer.

(c) OPEN SEASON.—An enrollee, participant, or beneficiary, may change to the offering provided under this section only during a time period determined by the health insurance issuer or group health plan. Such time period shall occur at least annually.

SEC. 112. CHOICE OF HEALTH CARE PROFESSIONAL.

(a) PRIMARY CARE.—If a group health plan, or a health insurance issuer that offers health insurance coverage, requires or provides for designation by a participant, beneficiary, or enrollee of a participating primary care provider, then the plan or issuer shall permit each participant, beneficiary, and enrollee to designate any participating primary care provider who is available to accept such individual.

(b) SPECIALISTS.—

(1) IN GENERAL.—Subject to paragraph (2), a group health plan and a health insurance issuer that offers health insurance coverage shall permit each participant, beneficiary, or enrollee to receive medically necessary or appropriate specialty care, pursu-

ant to appropriate referral procedures, from any qualified participating health care professional who is available to accept such individual for such care.

(2) LIMITATION.—Paragraph (1) shall not apply to specialty care if the plan or issuer clearly informs participants, beneficiaries, and enrollees of the limitations on choice of participating health care professionals with respect to such care.

(3) CONSTRUCTION.—Nothing in this subsection shall be construed as affecting the application of section 114 (relating to access to specialty care).

SEC. 113. ACCESS TO EMERGENCY CARE.

(a) COVERAGE OF EMERGENCY SERVICES.—

(1) IN GENERAL.—If a group health plan, or health insurance coverage offered by a health insurance issuer, provides or covers any benefits with respect to services in an emergency department of a hospital, the plan or issuer shall cover emergency services (as defined in paragraph (2)(B))—

(A) without the need for any prior authorization determination;

(B) whether the health care provider furnishing such services is a participating provider with respect to such services;

(C) in a manner so that, if such services are provided to a participant, beneficiary, or enrollee—

(i) by a nonparticipating health care provider with or without prior authorization, or

(ii) by a participating health care provider without prior authorization,

the participant, beneficiary, or enrollee is not liable for amounts that exceed the amounts of liability that would be incurred if the services were provided by a participating health care provider with prior authorization; and

(D) without regard to any other term or condition of such coverage (other than exclusion or coordination of benefits, or an affiliation or waiting period, permitted under section 2701 of the Public Health Service Act, section 701 of the Employee Retirement Income Security Act of 1974, or section 9801 of the Internal Revenue Code of 1986, and other than applicable cost-sharing).

(2) DEFINITIONS.—In this section:

(A) EMERGENCY MEDICAL CONDITION.—The term ''emergency medical condition'' means

a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in a condition described in clause (i), (ii), or (iii) of section 1867(e)(1)(A) of the Social Security Act.

(B) EMERGENCY SERVICES.—The term ''emergency services'' means, with respect to an emergency medical condition—

(i) a medical screening examination (as required under section 1867 of the Social Security Act) that is within the capability of the emergency department of a hospital, including ancillary services routinely available to the emergency department to evaluate such emergency medical condition, and

(ii) within the capabilities of the staff and facilities available at the hospital, such further medical examination and treatment as are required under section 1867 of such Act to stabilize the patient.

(C) STABILIZE.—The term ''to stabilize'', with respect to an emergency medical condition (as defined in subparagraph (A)), has the meaning give in section 1867(e)(3) of the Social Security Act (42 U.S.C. 1395dd(e)(3)).

(b) REIMBURSEMENT FOR MAINTENANCE CARE AND POST-STABILIZATION CARE.—A group health plan, and health insurance coverage offered by a health insurance issuer, must provide reimbursement for maintenance care and post-stabilization care in accordance with the requirements of section 1852(d)(2) of the Social Security Act (42 U.S.C. 1395w–22(d)(2)). Such reimbursement shall be provided in a manner consistent with subsection (a)(1)(C).

(c) COVERAGE OF EMERGENCY AMBULANCE SERVICES.—

(1) IN GENERAL.—If a group health plan, or health insurance coverage provided by a health insurance issuer, provides any benefits with respect to ambulance services and emergency services, the plan or issuer shall cover emergency ambulance services (as defined in paragraph (2)) furnished under the plan or coverage under the same terms and conditions under subparagraphs (A) through (D) of subsection (a)(1) under which coverage is provided for emergency services.

(2) EMERGENCY AMBULANCE SERVICES.—For purposes of this subsection, the term ''emergency ambulance services'' means ambulance services (as defined for purposes of section 1861(s)(7) of the Social Security Act) furnished to transport an individual who has an emergency medical condition (as defined in subsection (a)(2)(A)) to a hospital for the receipt of emergency services (as defined in subsection (a)(2)(B)) in a case in which the emergency services are covered under the plan or coverage pursuant to subsection (a)(1) and a prudent layperson, with an average knowledge of health and medicine, could reasonably expect that the absence of such transport would result in placing the health of the individual in serious jeopardy, serious impairment of bodily function, or serious dysfunction of any bodily organ or part.

SEC. 114. TIMELY ACCESS TO SPECIALISTS.

(a) TIMELY ACCESS.—

(1) IN GENERAL.—A group health plan or health insurance issuer offering health insurance coverage shall ensure that participants, beneficiaries, and enrollees receive timely access to specialists who are appropriate to the condition of, and accessible to, the participant, beneficiary, or enrollee, when

such specialty care is a covered benefit under the plan or coverage.

(2) RULE OF CONSTRUCTION.—Nothing in paragraph (1) shall be construed—

(A) to require the coverage under a group health plan or health insurance coverage of benefits or services;

(B) to prohibit a plan or issuer from including providers in the network only to the extent necessary to meet the needs of the plan's or issuer's participants, beneficiaries, or enrollees; or

(C) to override any State licensure or scope-of-practice law.

(3) ACCESS TO CERTAIN PROVIDERS.—

(A) IN GENERAL.—With respect to specialty care under this section, if a participating specialist is not available and qualified to provide such care to the participant, beneficiary, or enrollee, the plan or issuer shall provide for coverage of such care by a nonparticipating specialist.

(B) TREATMENT OF NONPARTICIPATING PROVIDERS.—If a participant, beneficiary, or enrollee receives care from a nonparticipating

specialist pursuant to subparagraph (A), such specialty care shall be provided at no additional cost to the participant, beneficiary, or enrollee beyond what the participant, beneficiary, or enrollee would otherwise pay for such specialty care if provided by a participating specialist.

(b) REFERRALS.—

(1) AUTHORIZATION.—A group health plan or health insurance issuer may require an authorization in order to obtain coverage for specialty services under this section. Any such authorization—

(A) shall be for an appropriate duration of time or number of referrals; and

(B) may not be refused solely because the authorization involves services of a nonparticipating specialist (described in subsection (a)(3)).

(2) REFERRALS FOR ONGOING SPECIAL CONDITIONS.—

(A) IN GENERAL.—A group health plan or health insurance issuer shall permit a participant, beneficiary, or enrollee who has an ongoing special condition (as defined in subparagraph (B)) to receive a referral to a specialist for the treatment of such condition and such

specialist may authorize such referrals, procedures, tests, and other medical services with respect to such condition, or coordinate the care for such condition, subject to the terms of a treatment plan (if any) referred to in subsection (c) with respect to the condition.

(B) ONGOING SPECIAL CONDITION DEFINED.—In this subsection, the term ''ongoing special condition'' means a condition or disease that—

(i) is life-threatening, degenerative, potentially disabling, or congenital; and

(ii) requires specialized medical care over a prolonged period of time.

(c) TREATMENT PLANS.—

(1) IN GENERAL.—A group health plan or health insurance issuer may require that the specialty care be provided—

(A) pursuant to a treatment plan, but only if the treatment plan—

(i) is developed by the specialist, in consultation with the case manager or primary care provider, and the participant, beneficiary, or enrollee, and

(ii) is approved by the plan or issuer in a timely manner, if the plan or issuer requires such approval; and

(B) in accordance with applicable quality assurance and utilization review standards of the plan or issuer.

(2) NOTIFICATION.—Nothing in paragraph (1) shall be construed as prohibiting a plan or issuer from requiring the specialist to provide the plan or issuer with regular updates on the specialty care provided, as well as all other reasonably necessary medical information.

(d) SPECIALIST DEFINED.—For purposes of this section, the term ''specialist'' means, with respect to the condition of the participant, beneficiary, or enrollee, a health care professional, facility, or center that has adequate expertise through appropriate training and experience (including, in the case of a child, appropriate pediatric expertise) to provide high quality care in treating the condition.

SEC. 115. PATIENT ACCESS TO OBSTETRIC AND GYNECOLOGICAL CARE.

(a) GENERAL RIGHTS.—

(1) DIRECT ACCESS.—A group health plan, or health insurance issuer offering health insurance coverage, described in subsection (b) may not re-

quire authorization or referral by the plan, issuer, or any person (including a primary care provider described in subsection (b)(2)) in the case of a female participant, beneficiary, or enrollee who seeks coverage for obstetrical or gynecological care provided by a participating health care professional who specializes in obstetrics or gynecology.

(2) OBSTETRICAL AND GYNECOLOGICAL CARE.—A group health plan or health insurance issuer described in subsection (b) shall treat the provision of obstetrical and gynecological care, and the ordering of related obstetrical and gynecological items and services, pursuant to the direct access described under paragraph (1), by a participating health care professional who specializes in obstetrics or gynecology as the authorization of the primary care provider.

(b) APPLICATION OF SECTION.—A group health plan, or health insurance issuer offering health insurance coverage, described in this subsection is a group health plan or coverage that—

(1) provides coverage for obstetric or gynecologic care; and

(2) requires the designation by a participant, beneficiary, or enrollee of a participating primary care provider.

(c) CONSTRUCTION.—Nothing in subsection (a) shall be construed to—

(1) waive any exclusions of coverage under the terms and conditions of the plan or health insurance coverage with respect to coverage of obstetrical or gynecological care; or

(2) preclude the group health plan or health insurance issuer involved from requiring that the obstetrical or gynecological provider notify the primary health care professional or the plan or issuer of treatment decisions.

SEC. 116. ACCESS TO PEDIATRIC CARE.

(a) PEDIATRIC CARE.—In the case of a person who has a child who is a participant, beneficiary, or enrollee under a group health plan, or health insurance coverage offered by a health insurance issuer, if the plan or issuer requires or provides for the designation of a participating primary care provider for the child, the plan or issuer shall permit such person to designate a physician (allopathic or osteopathic) who specializes in pediatrics as the child's primary care provider if such provider participates in the network of the plan or issuer.

(b) CONSTRUCTION.—Nothing in subsection (a) shall be construed to waive any exclusions of coverage under the terms and conditions of the plan or health insurance coverage with respect to coverage of pediatric care.

SEC. 117. CONTINUITY OF CARE.

(a) TERMINATION OF PROVIDER.—

(1) IN GENERAL.—If—

(A) a contract between a group health plan, or a health insurance issuer offering health insurance coverage, and a treating health care provider is terminated (as defined in paragraph (e)(4)), or

(B) benefits or coverage provided by a health care provider are terminated because of a change in the terms of provider participation in such plan or coverage,

the plan or issuer shall meet the requirements of paragraph (3) with respect to each continuing care patient.

(2) TREATMENT OF TERMINATION OF CONTRACT WITH HEALTH INSURANCE ISSUER.—If a contract for the provision of health insurance coverage between a group health plan and a health insurance issuer is terminated and, as a result of such termination, coverage of services of a health care

provider is terminated with respect to an individual, the provisions of paragraph (1) (and the succeeding provisions of this section) shall apply under the plan in the same manner as if there had been a contract between the plan and the provider that had been terminated, but only with respect to benefits that are covered under the plan after the contract termination.

(3) REQUIREMENTS.—The requirements of this paragraph are that the plan or issuer—

(A) notify the continuing care patient involved, or arrange to have the patient notified pursuant to subsection (d)(2), on a timely basis of the termination described in paragraph (1) (or paragraph (2), if applicable) and the right to elect continued transitional care from the provider under this section;

(B) provide the patient with an opportunity to notify the plan or issuer of the patient's need for transitional care; and

(C) subject to subsection (c), permit the patient to elect to continue to be covered with respect to the course of treatment by such provider with the provider's consent during a tran-

sitional period (as provided for under subsection (b)).

(4) CONTINUING CARE PATIENT.—For purposes of this section, the term ''continuing care patient'' means a participant, beneficiary, or enrollee who—

(A) is undergoing a course of treatment for a serious and complex condition from the provider at the time the plan or issuer receives or provides notice of provider, benefit, or coverage termination described in paragraph (1) (or paragraph (2), if applicable);

(B) is undergoing a course of institutional or inpatient care from the provider at the time of such notice;

(C) is scheduled to undergo non-elective surgery from the provider at the time of such notice;

(D) is pregnant and undergoing a course of treatment for the pregnancy from the provider at the time of such notice; or

(E) is or was determined to be terminally ill (as determined under section 1861(dd)(3)(A) of the Social Security Act) at the time of such notice, but only with respect to a provider that

was treating the terminal illness before the date of such notice.

(b) TRANSITIONAL PERIODS.—

(1) SERIOUS AND COMPLEX CONDITIONS.—The transitional period under this subsection with respect to a continuing care patient described in subsection (a)(4)(A) shall extend for up to 90 days (as determined by the treating health care professional) from the date of the notice described in subsection (a)(3)(A).

(2) INSTITUTIONAL OR INPATIENT CARE.—The transitional period under this subsection for a continuing care patient described in subsection (a)(4)(B) shall extend until the earlier of—

(A) the expiration of the 90-day period beginning on the date on which the notice under subsection (a)(3)(A) is provided; or

(B) the date of discharge of the patient from such care or the termination of the period of institutionalization, or, if later, the date of completion of reasonable follow-up care.

(3) SCHEDULED NON-ELECTIVE SURGERY.—The transitional period under this subsection for a continuing care patient described in subsection (a)(4)(C) shall extend until the completion of the

surgery involved and post-surgical follow-up care relating to the surgery and occurring within 90 days after the date of the surgery.

(4) PREGNANCY.—The transitional period under this subsection for a continuing care patient described in subsection (a)(4)(D) shall extend through the provision of post-partum care directly related to the delivery.

(5) TERMINAL ILLNESS.—The transitional period under this subsection for a continuing care patient described in subsection (a)(4)(E) shall extend for the remainder of the patient's life for care that is directly related to the treatment of the terminal illness or its medical manifestations.

(c) PERMISSIBLE TERMS AND CONDITIONS.—A group health plan or health insurance issuer may condition coverage of continued treatment by a provider under this section upon the provider agreeing to the following terms and conditions:

(1) The treating health care provider agrees to accept reimbursement from the plan or issuer and continuing care patient involved (with respect to cost-sharing) at the rates applicable prior to the start of the transitional period as payment in full (or, in the case described in subsection (a)(2), at the

rates applicable under the replacement plan or coverage after the date of the termination of the contract with the group health plan or health insurance issuer) and not to impose cost-sharing with respect to the patient in an amount that would exceed the cost-sharing that could have been imposed if the contract referred to in subsection (a)(1) had not been terminated.

(2) The treating health care provider agrees to adhere to the quality assurance standards of the plan or issuer responsible for payment under paragraph (1) and to provide to such plan or issuer necessary medical information related to the care provided.

(3) The treating health care provider agrees otherwise to adhere to such plan's or issuer's policies and procedures, including procedures regarding referrals and obtaining prior authorization and providing services pursuant to a treatment plan (if any) approved by the plan or issuer.

(d) RULES OF CONSTRUCTION.—Nothing in this section shall be construed—

(1) to require the coverage of benefits which would not have been covered if the provider involved remained a participating provider; or

(2) with respect to the termination of a contract under subsection (a) to prevent a group health plan or health insurance issuer from requiring that the health care provider—

(A) notify participants, beneficiaries, or enrollees of their rights under this section; or

(B) provide the plan or issuer with the name of each participant, beneficiary, or enrollee who the provider believes is a continuing care patient.

(e) DEFINITIONS.—In this section:

(1) CONTRACT.—The term ''contract'' includes, with respect to a plan or issuer and a treating health care provider, a contract between such plan or issuer and an organized network of providers that includes the treating health care provider, and (in the case of such a contract) the contract between the treating health care provider and the organized network.

(2) HEALTH CARE PROVIDER.—The term ''health care provider'' or ''provider'' means—

(A) any individual who is engaged in the delivery of health care services in a State and who is required by State law or regulation to be

licensed or certified by the State to engage in the delivery of such services in the State; and

(B) any entity that is engaged in the delivery of health care services in a State and that, if it is required by State law or regulation to be licensed or certified by the State to engage in the delivery of such services in the State, is so licensed.

(3) SERIOUS AND COMPLEX CONDITION.—The term ''serious and complex condition'' means, with respect to a participant, beneficiary, or enrollee under the plan or coverage—

(A) in the case of an acute illness, a condition that is serious enough to require specialized medical treatment to avoid the reasonable possibility of death or permanent harm; or

(B) in the case of a chronic illness or condition, is an ongoing special condition (as defined in section 114(b)(2)(B)).

(4) TERMINATED.—The term ''terminated'' includes, with respect to a contract, the expiration or nonrenewal of the contract, but does not include a termination of the contract for failure to meet applicable quality standards or for fraud.

SEC. 118. ACCESS TO NEEDED PRESCRIPTION DRUGS.

(a) IN GENERAL.—To the extent that a group health plan, or health insurance coverage offered by a health insurance issuer, provides coverage for benefits with respect to prescription drugs, and limits such coverage to drugs included in a formulary, the plan or issuer shall—

(1) ensure the participation of physicians and pharmacists in developing and reviewing such formulary;

(2) provide for disclosure of the formulary to providers; and

(3) in accordance with the applicable quality assurance and utilization review standards of the plan or issuer, provide for exceptions from the formulary limitation when a non-formulary alternative is medically necessary and appropriate and, in the case of such an exception, apply the same cost-sharing requirements that would have applied in the case of a drug covered under the formulary.

(b) COVERAGE OF APPROVED DRUGS AND MEDICAL DEVICES.—

(1) IN GENERAL.—A group health plan (or health insurance coverage offered in connection with such a plan) that provides any coverage of prescription drugs or medical devices shall not deny coverage

of such a drug or device on the basis that the use is investigational, if the use—

(A) in the case of a prescription drug—

(i) is included in the labeling authorized by the application in effect for the drug pursuant to subsection (b) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act, without regard to any postmarketing requirements that may apply under such Act; or

(ii) is included in the labeling authorized by the application in effect for the drug under section 351 of the Public Health Service Act, without regard to any postmarketing requirements that may apply pursuant to such section; or

(B) in the case of a medical device, is included in the labeling authorized by a regulation under subsection (d) or (3) of section 513 of the Federal Food, Drug, and Cosmetic Act, an order under subsection (f) of such section, or an application approved under section 515 of such Act, without regard to any postmarketing requirements that may apply under such Act.

(2) CONSTRUCTION.—Nothing in this subsection shall be construed as requiring a group health plan (or health insurance coverage offered in connection with such a plan) to provide any coverage of prescription drugs or medical devices.

SEC. 119. COVERAGE FOR INDIVIDUALS PARTICIPATING IN APPROVED CLINICAL TRIALS.

(a) COVERAGE.—

(1) IN GENERAL.—If a group health plan, or health insurance issuer that is providing health insurance coverage, provides coverage to a qualified individual (as defined in subsection (b)), the plan or issuer—

(A) may not deny the individual participation in the clinical trial referred to in subsection (b)(2);

(B) subject to subsection (c), may not deny (or limit or impose additional conditions on) the coverage of routine patient costs for items and services furnished in connection with participation in the trial; and

(C) may not discriminate against the individual on the basis of the enrollee's participation in such trial.

(2) EXCLUSION OF CERTAIN COSTS.—For purposes of paragraph (1)(B), routine patient costs do not include the cost of the tests or measurements conducted primarily for the purpose of the clinical trial involved.

(3) USE OF IN-NETWORK PROVIDERS.—If one or more participating providers is participating in a clinical trial, nothing in paragraph (1) shall be construed as preventing a plan or issuer from requiring that a qualified individual participate in the trial through such a participating provider if the provider will accept the individual as a participant in the trial.

(b) QUALIFIED INDIVIDUAL DEFINED.—For purposes of subsection (a), the term ''qualified individual'' means an individual who is a participant or beneficiary in a group health plan, or who is an enrollee under health insurance coverage, and who meets the following conditions:

(1)(A) The individual has a life-threatening or serious illness for which no standard treatment is effective.

(B) The individual is eligible to participate in an approved clinical trial according to the trial protocol with respect to treatment of such illness.

(C) The individual's participation in the trial offers meaningful potential for significant clinical benefit for the individual.

(2) Either—

(A) the referring physician is a participating health care professional and has concluded that the individual's participation in such trial would be appropriate based upon the individual meeting the conditions described in paragraph (1); or

(B) the participant, beneficiary, or enrollee provides medical and scientific information establishing that the individual's participation in such trial would be appropriate based upon the individual meeting the conditions described in paragraph (1).

(c) PAYMENT.—

(1) IN GENERAL.—Under this section a group health plan or health insurance issuer shall provide for payment for routine patient costs described in subsection (a)(2) but is not required to pay for costs of items and services that are reasonably expected (as determined by the appropriate Secretary) to be paid for by the sponsors of an approved clinical trial.

(2) PAYMENT RATE.—In the case of covered items and services provided by—

(A) a participating provider, the payment rate shall be at the agreed upon rate; or

(B) a nonparticipating provider, the payment rate shall be at the rate the plan or issuer would normally pay for comparable services under subparagraph (A).

(d) APPROVED CLINICAL TRIAL DEFINED.—

(1) IN GENERAL.—In this section, the term ''approved clinical trial'' means a clinical research study or clinical investigation approved and funded (which may include funding through in-kind contributions) by one or more of the following:

(A) The National Institutes of Health.

(B) A cooperative group or center of the National Institutes of Health.

(C) The Food and Drug Administration.

(D) Either of the following if the conditions described in paragraph (2) are met:

(i) The Department of Veterans Affairs.

(ii) The Department of Defense.

(2) CONDITIONS FOR DEPARTMENTS.—The conditions described in this paragraph, for a study

or investigation conducted by a Department, are that the study or investigation has been reviewed and approved through a system of peer review that the appropriate Secretary determines—

(A) to be comparable to the system of peer review of studies and investigations used by the National Institutes of Health; and

(B) assures unbiased review of the highest scientific standards by qualified individuals who have no interest in the outcome of the review.

(e) CONSTRUCTION.—Nothing in this section shall be construed to limit a plan's or issuer's coverage with respect to clinical trials.

SEC. 120. REQUIRED COVERAGE FOR MINIMUM HOSPITAL STAY FOR MASTECTOMIES AND LYMPH NODE DISSECTIONS FOR THE TREATMENT OF BREAST CANCER AND COVERAGE FOR SECONDARY CONSULTATIONS.

(a) INPATIENT CARE.—

(1) IN GENERAL.—A group health plan, and a health insurance issuer providing health insurance coverage, that provides medical and surgical benefits shall ensure that inpatient coverage with respect to the treatment of breast cancer is provided for a period of time as is determined by the attending physi-

cian, in consultation with the patient, to be medically necessary and appropriate following—

(A) a mastectomy;

(B) a lumpectomy; or

(C) a lymph node dissection for the treatment of breast cancer.

(2) EXCEPTION.—Nothing in this section shall be construed as requiring the provision of inpatient coverage if the attending physician and patient determine that a shorter period of hospital stay is medically appropriate.

(b) PROHIBITION ON CERTAIN MODIFICATIONS.—In implementing the requirements of this section, a group health plan, and a health insurance issuer providing health insurance coverage, may not modify the terms and conditions of coverage based on the determination by a participant, beneficiary, or enrollee to request less than the minimum coverage required under subsection (a).

(c) SECONDARY CONSULTATIONS.—

(1) IN GENERAL.—A group health plan, and a health insurance issuer providing health insurance coverage, that provides coverage with respect to medical and surgical services provided in relation to the diagnosis and treatment of cancer shall ensure that full coverage is provided for secondary consulta-

tions by specialists in the appropriate medical fields (including pathology, radiology, and oncology) to confirm or refute such diagnosis. Such plan or issuer shall ensure that full coverage is provided for such secondary consultation whether such consultation is based on a positive or negative initial diagnosis. In any case in which the attending physician certifies in writing that services necessary for such a secondary consultation are not sufficiently available from specialists operating under the plan or coverage with respect to whose services coverage is otherwise provided under such plan or by such issuer, such plan or issuer shall ensure that coverage is provided with respect to the services necessary for the secondary consultation with any other specialist selected by the attending physician for such purpose at no additional cost to the individual beyond that which the individual would have paid if the specialist was participating in the network of the plan or issuer.

(2) EXCEPTION.—Nothing in paragraph (1) shall be construed as requiring the provision of secondary consultations where the patient determines not to seek such a consultation.

(d) PROHIBITION ON PENALTIES OR INCENTIVES.—A group health plan, and a health insurance issuer providing health insurance coverage, may not—

(1) penalize or otherwise reduce or limit the reimbursement of a provider or specialist because the provider or specialist provided care to a participant, beneficiary, or enrollee in accordance with this section;

(2) provide financial or other incentives to a physician or specialist to induce the physician or specialist to keep the length of inpatient stays of patients following a mastectomy, lumpectomy, or a lymph node dissection for the treatment of breast cancer below certain limits or to limit referrals for secondary consultations; or

(3) provide financial or other incentives to a physician or specialist to induce the physician or specialist to refrain from referring a participant, beneficiary, or enrollee for a secondary consultation that would otherwise be covered by the plan or coverage involved under subsection (c).

Subtitle C—Access to Information

SEC. 121. PATIENT ACCESS TO INFORMATION.

(a) REQUIREMENT—

(1) DISCLOSURE.—

(A) IN GENERAL.—A group health plan, and a health insurance issuer that provides coverage in connection with health insurance coverage, shall provide for the disclosure to participants, beneficiaries, and enrollees—

(i) of the information described in subsection (b) at the time of the initial enrollment of the participant, beneficiary, or enrollee under the plan or coverage;

(ii) of such information on an annual basis—

(I) in conjunction with the election period of the plan or coverage if the plan or coverage has such an election period; or

(II) in the case of a plan or coverage that does not have an election period, in conjunction with the beginning of the plan or coverage year; and

(iii) of information relating to any material reduction to the benefits or information described in such subsection or subsection (c), in the form of a notice provided not later than 30 days before the date on which the reduction takes effect.

(B) PARTICIPANTS, BENEFICIARIES, AND ENROLLEES.—The disclosure required under subparagraph (A) shall be provided—

(i) jointly to each participant, beneficiary, and enrollee who reside at the same address; or

(ii) in the case of a beneficiary or enrollee who does not reside at the same address as the participant or another enrollee, separately to the participant or other enrollees and such beneficiary or enrollee.

(2) PROVISION OF INFORMATION.—Information shall be provided to participants, beneficiaries, and enrollees under this section at the last known address maintained by the plan or issuer with respect to such participants, beneficiaries, or enrollees, to the extent that such information is provided to participants, beneficiaries, or enrollees via the United States Postal Service or other private delivery service.

(b) REQUIRED INFORMATION.—The informational materials to be distributed under this section shall include for each option available under the group health plan or health insurance coverage the following:

(1) BENEFITS.—A description of the covered benefits, including—

(A) any in- and out-of-network benefits;

(B) specific preventive services covered under the plan or coverage if such services are covered;

(C) any specific exclusions or express limitations of benefits described in section 104(b)(3)(C);

(D) any other benefit limitations, including any annual or lifetime benefit limits and any monetary limits or limits on the number of visits, days, or services, and any specific coverage exclusions; and

(E) any definition of medical necessity used in making coverage determinations by the plan, issuer, or claims administrator.

(2) COST SHARING.—A description of any cost-sharing requirements, including—

(A) any premiums, deductibles, coinsurance, copayment amounts, and liability for balance billing, for which the participant, beneficiary, or enrollee will be responsible under each option available under the plan;

(B) any maximum out-of-pocket expense for which the participant, beneficiary, or enrollee may be liable;

(C) any cost-sharing requirements for out-of-network benefits or services received from nonparticipating providers; and

(D) any additional cost-sharing or charges for benefits and services that are furnished without meeting applicable plan or coverage requirements, such as prior authorization or precertification.

(3) SERVICE AREA.—A description of the plan or issuer's service area, including the provision of any out-of-area coverage.

(4) PARTICIPATING PROVIDERS.—A directory of participating providers (to the extent a plan or issuer provides coverage through a network of providers) that includes, at a minimum, the name, address, and telephone number of each participating provider, and information about how to inquire whether a participating provider is currently accepting new patients.

(5) CHOICE OF PRIMARY CARE PROVIDER.—A description of any requirements and procedures to be used by participants, beneficiaries, and enrollees

in selecting, accessing, or changing their primary care provider, including providers both within and outside of the network (if the plan or issuer permits out-of-network services), and the right to select a pediatrician as a primary care provider under section 116 for a participant, beneficiary, or enrollee who is a child if such section applies.

(6) PREAUTHORIZATION REQUIREMENTS.—A description of the requirements and procedures to be used to obtain preauthorization for health services, if such preauthorization is required.

(7) EXPERIMENTAL AND INVESTIGATIONAL TREATMENTS.—A description of the process for determining whether a particular item, service, or treatment is considered experimental or investigational, and the circumstances under which such treatments are covered by the plan or issuer.

(8) SPECIALTY CARE.—A description of the requirements and procedures to be used by participants, beneficiaries, and enrollees in accessing specialty care and obtaining referrals to participating and nonparticipating specialists, including any limitations on choice of health care professionals referred to in section 112(b)(2) and the right to timely

access to specialists care under section 114 if such section applies.

(9) CLINICAL TRIALS.—A description the circumstances and conditions under which participation in clinical trials is covered under the terms and conditions of the plan or coverage, and the right to obtain coverage for approved clinical trials under section 119 if such section applies.

(10) PRESCRIPTION DRUGS.—To the extent the plan or issuer provides coverage for prescription drugs, a statement of whether such coverage is limited to drugs included in a formulary, a description of any provisions and cost-sharing required for obtaining on- and off-formulary medications, and a description of the rights of participants, beneficiaries, and enrollees in obtaining access to access to prescription drugs under section 118 if such section applies.

(11) EMERGENCY SERVICES.—A summary of the rules and procedures for accessing emergency services, including the right of a participant, beneficiary, or enrollee to obtain emergency services under the prudent layperson standard under section 113, if such section applies, and any educational in-

formation that the plan or issuer may provide regarding the appropriate use of emergency services.

(12) CLAIMS AND APPEALS.—A description of the plan or issuer's rules and procedures pertaining to claims and appeals, a description of the rights (including deadlines for exercising rights) of participants, beneficiaries, and enrollees under subtitle A in obtaining covered benefits, filing a claim for benefits, and appealing coverage decisions internally and externally (including telephone numbers and mailing addresses of the appropriate authority), and a description of any additional legal rights and remedies available under section 502 of the Employee Retirement Income Security Act of 1974 and applicable State law.

(13) ADVANCE DIRECTIVES AND ORGAN DONATION.—A description of procedures for advance directives and organ donation decisions if the plan or issuer maintains such procedures.

(14) INFORMATION ON PLANS AND ISSUERS.—The name, mailing address, and telephone number or numbers of the plan administrator and the issuer to be used by participants, beneficiaries, and enrollees seeking information about plan or coverage benefits and services, payment of a claim, or authoriza-

tion for services and treatment. Notice of whether the benefits under the plan or coverage are provided under a contract or policy of insurance issued by an issuer, or whether benefits are provided directly by the plan sponsor who bears the insurance risk.

(15) TRANSLATION SERVICES.—A summary description of any translation or interpretation services (including the availability of printed information in languages other than English, audio tapes, or information in Braille) that are available for non-English speakers and participants, beneficiaries, and enrollees with communication disabilities and a description of how to access these items or services.

(16) ACCREDITATION INFORMATION.—Any information that is made public by accrediting organizations in the process of accreditation if the plan or issuer is accredited, or any additional quality indicators (such as the results of enrollee satisfaction surveys) that the plan or issuer makes public or makes available to participants, beneficiaries, and enrollees.

(17) NOTICE OF REQUIREMENTS.—A description of any rights of participants, beneficiaries, and enrollees that are established by the Bipartisan Patient Protection Act of 2001 (excluding those described in paragraphs (1) through (16)) if such sec-

tions apply. The description required under this paragraph may be combined with the notices of the type described in sections 711(d), 713(b), or 606(a)(1) of the Employee Retirement Income Security Act of 1974 and with any other notice provision that the appropriate Secretary determines may be combined, so long as such combination does not result in any reduction in the information that would otherwise be provided to the recipient.

(18) AVAILABILITY OF ADDITIONAL INFORMATION.—A statement that the information described in subsection (c), and instructions on obtaining such information (including telephone numbers and, if available, Internet websites), shall be made available upon request.

(c) ADDITIONAL INFORMATION.—The informational materials to be provided upon the request of a participant, beneficiary, or enrollee shall include for each option available under a group health plan or health insurance coverage the following:

(1) STATUS OF PROVIDERS.—The State licensure status of the plan or issuer's participating health care professionals and participating health care facilities, and, if available, the education, train-

ing, specialty qualifications or certifications of such professionals.

(2) COMPENSATION METHODS.—A summary description by category of the applicable methods (such as capitation, fee-for-service, salary, bundled payments, per diem, or a combination thereof) used for compensating prospective or treating health care professionals (including primary care providers and specialists) and facilities in connection with the provision of health care under the plan or coverage.

(3) PRESCRIPTION DRUGS.—Information about whether a specific prescription medication is included in the formulary of the plan or issuer, if the plan or issuer uses a defined formulary.

(4) EXTERNAL APPEALS INFORMATION.—Aggregate information on the number and outcomes of external medical reviews, relative to the sample size (such as the number of covered lives) under the plan or under the coverage of the issuer.

(d) MANNER OF DISCLOSURE.—The information described in this section shall be disclosed in an accessible medium and format that is calculated to be understood by an average participant or enrollee.

(e) RULES OF CONSTRUCTION.—Nothing in this section shall be construed to prohibit a group health plan,

or a health insurance issuer in connection with health insurance coverage, from—

(1) distributing any other additional information determined by the plan or issuer to be important or necessary in assisting participants, beneficiaries, and enrollees in the selection of a health plan or health insurance coverage; and

(2) complying with the provisions of this section by providing information in brochures, through the Internet or other electronic media, or through other similar means, so long as—

(A) the disclosure of such information in such form is in accordance with requirements as the appropriate Secretary may impose, and

(B) in connection with any such disclosure of information through the Internet or other electronic media—

(i) the recipient has affirmatively consented to the disclosure of such information in such form,

(ii) the recipient is capable of accessing the information so disclosed on the recipient's individual workstation or at the recipient's home,

(iii) the recipient retains an ongoing right to receive paper disclosure of such information and receives, in advance of any attempt at disclosure of such information to him or her through the Internet or other electronic media, notice in printed form of such ongoing right and of the proper software required to view information so disclosed, and

(iv) the plan administrator appropriately ensures that the intended recipient is receiving the information so disclosed and provides the information in printed form if the information is not received.

Subtitle D—Protecting the Doctor-Patient Relationship

SEC. 131. PROHIBITION OF INTERFERENCE WITH CERTAIN MEDICAL COMMUNICATIONS.

(a) GENERAL RULE.—The provisions of any contract or agreement, or the operation of any contract or agreement, between a group health plan or health insurance issuer in relation to health insurance coverage (including any partnership, association, or other organization that enters into or administers such a contract or agreement) and a health care provider (or group of health care pro-

viders) shall not prohibit or otherwise restrict a health care professional from advising such a participant, beneficiary, or enrollee who is a patient of the professional about the health status of the individual or medical care or treatment for the individual's condition or disease, regardless of whether benefits for such care or treatment are provided under the plan or coverage, if the professional is acting within the lawful scope of practice.

(b) NULLIFICATION.—Any contract provision or agreement that restricts or prohibits medical communications in violation of subsection (a) shall be null and void.

SEC. 132. PROHIBITION OF DISCRIMINATION AGAINST PROVIDERS BASED ON LICENSURE.

(a) IN GENERAL.—A group health plan, and a health insurance issuer with respect to health insurance coverage, shall not discriminate with respect to participation or indemnification as to any provider who is acting within the scope of the provider's license or certification under applicable State law, solely on the basis of such license or certification.

(b) CONSTRUCTION.—Subsection (a) shall not be construed—

(1) as requiring the coverage under a group health plan or health insurance coverage of a particular benefit or service or to prohibit a plan or

issuer from including providers only to the extent necessary to meet the needs of the plan's or issuer's participants, beneficiaries, or enrollees or from establishing any measure designed to maintain quality and control costs consistent with the responsibilities of the plan or issuer;

(2) to override any State licensure or scope-of-practice law; or

(3) as requiring a plan or issuer that offers network coverage to include for participation every willing provider who meets the terms and conditions of the plan or issuer.

SEC. 133. PROHIBITION AGAINST IMPROPER INCENTIVE ARRANGEMENTS.

(a) IN GENERAL.—A group health plan and a health insurance issuer offering health insurance coverage may not operate any physician incentive plan (as defined in subparagraph (B) of section 1876(i)(8) of the Social Security Act) unless the requirements described in clauses (i), (ii)(I), and (iii) of subparagraph (A) of such section are met with respect to such a plan.

(b) APPLICATION.—For purposes of carrying out paragraph (1), any reference in section 1876(i)(8) of the Social Security Act to the Secretary, an eligible organization, or an individual enrolled with the organization shall

be treated as a reference to the applicable authority, a group health plan or health insurance issuer, respectively, and a participant, beneficiary, or enrollee with the plan or organization, respectively.

(c) CONSTRUCTION.—Nothing in this section shall be construed as prohibiting all capitation and similar arrangements or all provider discount arrangements.

SEC. 134. PAYMENT OF CLAIMS.

A group health plan, and a health insurance issuer offering group health insurance coverage, shall provide for prompt payment of claims submitted for health care services or supplies furnished to a participant, beneficiary, or enrollee with respect to benefits covered by the plan or issuer, in a manner consistent with the provisions of section 1842(c)(2) of the Social Security Act (42 U.S.C. 1395u(c)(2)).

SEC. 135. PROTECTION FOR PATIENT ADVOCACY.

(a) PROTECTION FOR USE OF UTILIZATION REVIEW AND GRIEVANCE PROCESS.—A group health plan, and a health insurance issuer with respect to the provision of health insurance coverage, may not retaliate against a participant, beneficiary, enrollee, or health care provider based on the participant's, beneficiary's, enrollee's or provider's use of, or participation in, a utilization review process or a grievance process of the plan or issuer (including

an internal or external review or appeal process) under this title.

(b) PROTECTION FOR QUALITY ADVOCACY BY HEALTH CARE PROFESSIONALS.—

(1) IN GENERAL.—A group health plan or health insurance issuer may not retaliate or discriminate against a protected health care professional because the professional in good faith—

(A) discloses information relating to the care, services, or conditions affecting one or more participants, beneficiaries, or enrollees of the plan or issuer to an appropriate public regulatory agency, an appropriate private accreditation body, or appropriate management personnel of the plan or issuer; or

(B) initiates, cooperates, or otherwise participates in an investigation or proceeding by such an agency with respect to such care, services, or conditions.

If an institutional health care provider is a participating provider with such a plan or issuer or otherwise receives payments for benefits provided by such a plan or issuer, the provisions of the previous sentence shall apply to the provider in relation to care, services, or conditions affecting one or more patients

within an institutional health care provider in the same manner as they apply to the plan or issuer in relation to care, services, or conditions provided to one or more participants, beneficiaries, or enrollees; and for purposes of applying this sentence, any reference to a plan or issuer is deemed a reference to the institutional health care provider.

(2) GOOD FAITH ACTION.—For purposes of paragraph (1), a protected health care professional is considered to be acting in good faith with respect to disclosure of information or participation if, with respect to the information disclosed as part of the action—

(A) the disclosure is made on the basis of personal knowledge and is consistent with that degree of learning and skill ordinarily possessed by health care professionals with the same licensure or certification and the same experience;

(B) the professional reasonably believes the information to be true;

(C) the information evidences either a violation of a law, rule, or regulation, of an applicable accreditation standard, or of a generally recognized professional or clinical standard or

that a patient is in imminent hazard of loss of life or serious injury; and

(D) subject to subparagraphs (B) and (C) of paragraph (3), the professional has followed reasonable internal procedures of the plan, issuer, or institutional health care provider established for the purpose of addressing quality concerns before making the disclosure.

(3) EXCEPTION AND SPECIAL RULE.—

(A) GENERAL EXCEPTION.—Paragraph (1) does not protect disclosures that would violate Federal or State law or diminish or impair the rights of any person to the continued protection of confidentiality of communications provided by such law.

(B) NOTICE OF INTERNAL PROCEDURES.—Subparagraph (D) of paragraph (2) shall not apply unless the internal procedures involved are reasonably expected to be known to the health care professional involved. For purposes of this subparagraph, a health care professional is reasonably expected to know of internal procedures if those procedures have been made available to the professional through distribution or posting.

(C) INTERNAL PROCEDURE EXCEPTION.—Subparagraph (D) of paragraph (2) also shall not apply if—

(i) the disclosure relates to an imminent hazard of loss of life or serious injury to a patient;

(ii) the disclosure is made to an appropriate private accreditation body pursuant to disclosure procedures established by the body; or

(iii) the disclosure is in response to an inquiry made in an investigation or proceeding of an appropriate public regulatory agency and the information disclosed is limited to the scope of the investigation or proceeding.

(4) ADDITIONAL CONSIDERATIONS.—It shall not be a violation of paragraph (1) to take an adverse action against a protected health care professional if the plan, issuer, or provider taking the adverse action involved demonstrates that it would have taken the same adverse action even in the absence of the activities protected under such paragraph.

(5) NOTICE.—A group health plan, health insurance issuer, and institutional health care provider shall post a notice, to be provided or approved by the Secretary of Labor, setting forth excerpts from, or summaries of, the pertinent provisions of this subsection and information pertaining to enforcement of such provisions.

(6) CONSTRUCTIONS.—

(A) DETERMINATIONS OF COVERAGE.—Nothing in this subsection shall be construed to prohibit a plan or issuer from making a determination not to pay for a particular medical treatment or service or the services of a type of health care professional.

(B) ENFORCEMENT OF PEER REVIEW PROTOCOLS AND INTERNAL PROCEDURES.—Nothing in this subsection shall be construed to prohibit a plan, issuer, or provider from establishing and enforcing reasonable peer review or utilization review protocols or determining whether a protected health care professional has complied with those protocols or from establishing and enforcing internal procedures for the purpose of addressing quality concerns.

(C) RELATION TO OTHER RIGHTS.—Nothing in this subsection shall be construed to abridge rights of participants, beneficiaries, enrollees, and protected health care professionals under other applicable Federal or State laws.

(7) PROTECTED HEALTH CARE PROFESSIONAL DEFINED.—For purposes of this subsection, the term ''protected health care professional'' means an individual who is a licensed or certified health care professional and who—

(A) with respect to a group health plan or health insurance issuer, is an employee of the plan or issuer or has a contract with the plan or issuer for provision of services for which benefits are available under the plan or issuer; or

(B) with respect to an institutional health care provider, is an employee of the provider or has a contract or other arrangement with the provider respecting the provision of health care services.

Subtitle E—Definitions

SEC. 151. DEFINITIONS.

(a) INCORPORATION OF GENERAL DEFINITIONS.—Except as otherwise provided, the provisions of section 2791 of the Public Health Service Act shall apply for pur-

poses of this title in the same manner as they apply for purposes of title XXVII of such Act.

(b) SECRETARY.—Except as otherwise provided, the term ''Secretary'' means the Secretary of Health and Human Services, in consultation with the Secretary of Labor and the term ''appropriate Secretary'' means the Secretary of Health and Human Services in relation to carrying out this title under sections 2706 and 2751 of the Public Health Service Act and the Secretary of Labor in relation to carrying out this title under section 713 of the Employee Retirement Income Security Act of 1974.

(c) ADDITIONAL DEFINITIONS.—For purposes of this title:

(1) APPLICABLE AUTHORITY.—The term ''applicable authority'' means—

(A) in the case of a group health plan, the Secretary of Health and Human Services and the Secretary of Labor; and

(B) in the case of a health insurance issuer with respect to a specific provision of this title, the applicable State authority (as defined in section 2791(d) of the Public Health Service Act), or the Secretary of Health and Human Services, if such Secretary is enforcing such

provision under section 2722(a)(2) or 2761(a)(2) of the Public Health Service Act.

(3) ENROLLEE.—The term ''enrollee'' means, with respect to health insurance coverage offered by a health insurance issuer, an individual enrolled with the issuer to receive such coverage.

(4) GROUP HEALTH PLAN.—The term ''group health plan'' has the meaning given such term in section 733(a) of the Employee Retirement Income Security Act of 1974, except that such term includes a employee welfare benefit plan treated as a group health plan under section 732(d) of such Act or defined as such a plan under section 607(1) of such Act.

(5) HEALTH CARE PROFESSIONAL.—The term ''health care professional'' means an individual who is licensed, accredited, or certified under State law to provide specified health care services and who is operating within the scope of such licensure, accreditation, or certification.

(6) HEALTH CARE PROVIDER.—The term ''health care provider'' includes a physician or other health care professional, as well as an institutional or other facility or agency that provides health care services and that is licensed, accredited, or certified

to provide health care items and services under applicable State law.

(7) NETWORK.—The term ''network'' means, with respect to a group health plan or health insurance issuer offering health insurance coverage, the participating health care professionals and providers through whom the plan or issuer provides health care items and services to participants, beneficiaries, or enrollees.

(8) NONPARTICIPATING.—The term ''nonparticipating'' means, with respect to a health care provider that provides health care items and services to a participant, beneficiary, or enrollee under group health plan or health insurance coverage, a health care provider that is not a participating health care provider with respect to such items and services.

(9) PARTICIPATING.—The term ''participating'' means, with respect to a health care provider that provides health care items and services to a participant, beneficiary, or enrollee under group health plan or health insurance coverage offered by a health insurance issuer, a health care provider that furnishes such items and services under a contract or other arrangement with the plan or issuer.

(10) PRIOR AUTHORIZATION.—The term ''prior authorization'' means the process of obtaining prior approval from a health insurance issuer or group health plan for the provision or coverage of medical services.

(11) TERMS AND CONDITIONS.—The term ''terms and conditions'' includes, with respect to a group health plan or health insurance coverage, requirements imposed under this title with respect to the plan or coverage.

SEC. 152. PREEMPTION; STATE FLEXIBILITY; CONSTRUCTION.

(a) CONTINUED APPLICABILITY OF STATE LAW WITH RESPECT TO HEALTH INSURANCE ISSUERS.—

(1) IN GENERAL.—Subject to paragraph (2), this title shall not be construed to supersede any provision of State law which establishes, implements, or continues in effect any standard or requirement solely relating to health insurance issuers (in connection with group health insurance coverage or otherwise) except to the extent that such standard or requirement prevents the application of a requirement of this title.

(2) CONTINUED PREEMPTION WITH RESPECT TO GROUP HEALTH PLANS.—Nothing in this title

shall be construed to affect or modify the provisions of section 514 of the Employee Retirement Income Security Act of 1974 with respect to group health plans.

(3) CONSTRUCTION.—In applying this section, a State law that provides for equal access to, and availability of, all categories of licensed health care providers and services shall not be treated as preventing the application of any requirement of this title.

(b) APPLICATION OF SUBSTANTIALLY EQUIVALENT STATE LAWS.—

(1) IN GENERAL.—In the case of a State law that imposes, with respect to health insurance coverage offered by a health insurance issuer and with respect to a group health plan that is a non-Federal governmental plan, a requirement that is substantially equivalent (within the meaning of subsection (c)) to a patient protection requirement (as defined in paragraph (3)) and does not prevent the application of other requirements under this Act (except in the case of other substantially equivalent requirements), in applying the requirements of this title under section 2707 and 2753 (as applicable) of the

Public Health Service Act (as added by title II), subject to subsection (a)(2)—

(A) the State law shall not be treated as being superseded under subsection (a); and

(B) the State law shall apply instead of the patient protection requirement otherwise applicable with respect to health insurance coverage and non-Federal governmental plans.

(2) LIMITATION.—In the case of a group health plan covered under title I of the Employee Retirement Income Security Act of 1974, paragraph (1) shall be construed to apply only with respect to the health insurance coverage (if any) offered in connection with the plan.

(3) PATIENT PROTECTION REQUIREMENT DEFINED.—For purposes of this section, the term ''patient protection requirement'' means a requirement under this title, and includes (as a single requirement) a group or related set of requirements under a section or similar unit under this title.

(c) DETERMINATIONS OF SUBSTANTIAL EQUIVALENCE.—

(1) CERTIFICATION BY STATES.—A State may submit to the Secretary a certification that a State law provides for patient protections that are at least

substantially equivalent to one or more patient protection requirements. Such certification shall be accompanied by such information as may be required to permit the Secretary to make the determination described in paragraph (2)(A).

(2) REVIEW.—

(A) IN GENERAL.—The Secretary shall promptly review a certification submitted under paragraph (1) with respect to a State law to determine if the State law provides for at least substantially equivalent and effective patient protections to the patient protection requirement (or requirements) to which the law relates.

(B) APPROVAL DEADLINES.—

(i) INITIAL REVIEW.—Such a certification is considered approved unless the Secretary notifies the State in writing, within 90 days after the date of receipt of the certification, that the certification is disapproved (and the reasons for disapproval) or that specified additional information is needed to make the determination described in subparagraph (A).

(ii) ADDITIONAL INFORMATION.—With respect to a State that has been notified by the Secretary under clause (i) that specified additional information is needed to make the determination described in subparagraph (A), the Secretary shall make the determination within 60 days after the date on which such specified additional information is received by the Secretary.

(3) APPROVAL.—

(A) IN GENERAL.—The Secretary shall approve a certification under paragraph (1) unless—

(i) the State fails to provide sufficient information to enable the Secretary to make a determination under paragraph (2)(A); or

(ii) the Secretary determines that the State law involved does not provide for patient protections that are at least substantially equivalent to and as effective as the patient protection requirement (or requirements) to which the law relates.

(B) STATE CHALLENGE.—A State that has a certification disapproved by the Secretary under subparagraph (A) may challenge such disapproval in the appropriate United States district court.

(4) CONSTRUCTION.—Nothing in this subsection shall be construed as preventing the certification (and approval of certification) of a State law under this subsection solely because it provides for greater protections for patients than those protections otherwise required to establish substantial equivalence.

(d) DEFINITIONS.—For purposes of this section:

(1) STATE LAW.—The term ''State law'' includes all laws, decisions, rules, regulations, or other State action having the effect of law, of any State. A law of the United States applicable only to the District of Columbia shall be treated as a State law rather than a law of the United States.

(2) STATE.—The term ''State'' includes a State, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, the Northern Mariana Islands, any political subdivisions of such, or any agency or instrumentality of such.

SEC. 153. EXCLUSIONS.

(a) NO BENEFIT REQUIREMENTS.—Nothing in this title shall be construed to require a group health plan or a health insurance issuer offering health insurance coverage to include specific items and services under the terms of such a plan or coverage, other than those provided under the terms and conditions of such plan or coverage.

(b) EXCLUSION FROM ACCESS TO CARE MANAGED CARE PROVISIONS FOR FEE-FOR-SERVICE COVERAGE.—

(1) IN GENERAL.—The provisions of sections 111 through 117 shall not apply to a group health plan or health insurance coverage if the only coverage offered under the plan or coverage is fee-for-service coverage (as defined in paragraph (2)).

(2) FEE-FOR-SERVICE COVERAGE DEFINED.—For purposes of this subsection, the term ''fee-for-service coverage'' means coverage under a group health plan or health insurance coverage that—

(A) reimburses hospitals, health professionals, and other providers on a fee-for-service basis without placing the provider at financial risk;

(B) does not vary reimbursement for such a provider based on an agreement to contract

terms and conditions or the utilization of health care items or services relating to such provider;

(C) allows access to any provider that is lawfully authorized to provide the covered services and that agrees to accept the terms and conditions of payment established under the plan or by the issuer; and

(D) for which the plan or issuer does not require prior authorization before providing for any health care services.

SEC. 154. COVERAGE OF LIMITED SCOPE PLANS.

Only for purposes of applying the requirements of this title under sections 2707 and 2753 of the Public Health Service Act and section 714 of the Employee Retirement Income Security Act of 1974, section 2791(c)(2)(A), and section 733(c)(2)(A) of the Employee Retirement Income Security Act of 1974 shall be deemed not to apply.

SEC. 155. REGULATIONS.

The Secretaries of Health and Human Services and Labor shall issue such regulations as may be necessary or appropriate to carry out this title. Such regulations shall be issued consistent with section 104 of Health Insurance Portability and Accountability Act of 1996. Such Secretaries may promulgate any interim final rules as the

Secretaries determine are appropriate to carry out this title.

SEC. 156. INCORPORATION INTO PLAN OR COVERAGE DOCUMENTS.

The requirements of this title with respect to a group health plan or health insurance coverage are deemed to be incorporated into, and made a part of, such plan or the policy, certificate, or contract providing such coverage and are enforceable under law as if directly included in the documentation of such plan or such policy, certificate, or contract.

TITLE II—APPLICATION OF QUALITY CARE STANDARDS TO GROUP HEALTH PLANS AND HEALTH INSURANCE COVERAGE UNDER THE PUBLIC HEALTH SERVICE ACT

SEC. 201. APPLICATION TO GROUP HEALTH PLANS AND GROUP HEALTH INSURANCE COVERAGE.

(a) IN GENERAL.—Subpart 2 of part A of title XXVII of the Public Health Service Act is amended by adding at the end the following new section:

"SEC. 2707. PATIENT PROTECTION STANDARDS.

''Each group health plan shall comply with patient protection requirements under title I of the Bipartisan Pa-

tient Protection Act of 2001, and each health insurance issuer shall comply with patient protection requirements under such title with respect to group health insurance coverage it offers, and such requirements shall be deemed to be incorporated into this subsection.''.

(b) CONFORMING AMENDMENT.—Section 2721(b)(2)(A) of such Act (42 U.S.C. 300gg–21(b)(2)(A)) is amended by inserting ''(other than section 2707)'' after ''requirements of such subparts''.

SEC. 202. APPLICATION TO INDIVIDUAL HEALTH INSURANCE COVERAGE.

Part B of title XXVII of the Public Health Service Act is amended by inserting after section 2752 the following new section:

''SEC. 2753. PATIENT PROTECTION STANDARDS.

''Each health insurance issuer shall comply with patient protection requirements under title I of the Bipartisan Patient Protection Act of 2001 with respect to individual health insurance coverage it offers, and such requirements shall be deemed to be incorporated into this subsection.''.

TITLE III—AMENDMENTS TO THE EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974

SEC. 301. APPLICATION OF PATIENT PROTECTION STANDARDS TO GROUP HEALTH PLANS AND GROUP HEALTH INSURANCE COVERAGE UNDER THE EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974.

Subpart B of part 7 of subtitle B of title I of the Employee Retirement Income Security Act of 1974 is amended by adding at the end the following new section:

"SEC. 714. PATIENT PROTECTION STANDARDS.

"(a) IN GENERAL.—Subject to subsection (b), a group health plan (and a health insurance issuer offering group health insurance coverage in connection with such a plan) shall comply with the requirements of title I of the Bipartisan Patient Protection Act of 2001 (as in effect as of the date of the enactment of such Act), and such requirements shall be deemed to be incorporated into this subsection.

"(b) PLAN SATISFACTION OF CERTAIN REQUIREMENTS.—

"(1) SATISFACTION OF CERTAIN REQUIREMENTS THROUGH INSURANCE.—For purposes of

subsection (a), insofar as a group health plan provides benefits in the form of health insurance coverage through a health insurance issuer, the plan shall be treated as meeting the following requirements of title I of the Bipartisan Patient Protection Act of 2001 with respect to such benefits and not be considered as failing to meet such requirements because of a failure of the issuer to meet such requirements so long as the plan sponsor or its representatives did not cause such failure by the issuer:

''(A) Section 111 (relating to consumer choice option).

''(B) Section 112 (relating to choice of health care professional).

''(C) Section 113 (relating to access to emergency care).

''(D) Section 114 (relating to timely access to specialists).

''(E) Section 115 (relating to patient access to obstetrical and gynecological care).

''(F) Section 116 (relating to access to pediatric care).

''(G) Section 117 (relating to continuity of care), but only insofar as a replacement issuer assumes the obligation for continuity of care.

"(H) Section 118 (relating to access to needed prescription drugs).

"(I) Section 119 (relating to coverage for individuals participating in approved clinical trials).

"(J) Section 120 (relating to required coverage for minimum hospital stay for mastectomies and lymph node dissections for the treatment of breast cancer and coverage for secondary consultations).

"(K) Section 134 (relating to payment of claims).

"(2) INFORMATION.—With respect to information required to be provided or made available under section 121 of the Bipartisan Patient Protection Act of 2001, in the case of a group health plan that provides benefits in the form of health insurance coverage through a health insurance issuer, the Secretary shall determine the circumstances under which the plan is not required to provide or make available the information (and is not liable for the issuer's failure to provide or make available the information), if the issuer is obligated to provide and make available (or provides and makes available) such information.

''(3) INTERNAL APPEALS.—With respect to the internal appeals process required to be established under section 103 of such Act, in the case of a group health plan that provides benefits in the form of health insurance coverage through a health insurance issuer, the Secretary shall determine the circumstances under which the plan is not required to provide for such process and system (and is not liable for the issuer's failure to provide for such process and system), if the issuer is obligated to provide for (and provides for) such process and system.

''(4) EXTERNAL APPEALS.—Pursuant to rules of the Secretary, insofar as a group health plan enters into a contract with a qualified external appeal entity for the conduct of external appeal activities in accordance with section 104 of such Act, the plan shall be treated as meeting the requirement of such section and is not liable for the entity's failure to meet any requirements under such section.

''(5) APPLICATION TO PROHIBITIONS.—Pursuant to rules of the Secretary, if a health insurance issuer offers health insurance coverage in connection with a group health plan and takes an action in violation of any of the following sections of the Bipartisan Patient Protection Act of 2001, the group

health plan shall not be liable for such violation unless the plan caused such violation:

"(A) Section 131 (relating to prohibition of interference with certain medical communications).

"(B) Section 132 (relating to prohibition of discrimination against providers based on licensure).

"(C) Section 133 (relating to prohibition against improper incentive arrangements).

"(D) Section 135 (relating to protection for patient advocacy).

"(6) CONSTRUCTION.—Nothing in this subsection shall be construed to affect or modify the responsibilities of the fiduciaries of a group health plan under part 4 of subtitle B.

"(7) TREATMENT OF SUBSTANTIALLY EQUIVALENT STATE LAWS.—For purposes of applying this subsection, any reference in this subsection to a requirement in a section or other provision in the Bipartisan Patient Protection Act of 2001 with respect to a health insurance issuer is deemed to include a reference to a requirement under a State law that is substantially equivalent (as determined under section

152(c) of such Act) to the requirement in such section or other provisions.

''(8) APPLICATION TO CERTAIN PROHIBITIONS AGAINST RETALIATION.—With respect to compliance with the requirements of section 135(b)(1) of the Bipartisan Patient Protection Act of 2001, for purposes of this subtitle the term 'group health plan' is deemed to include a reference to an institutional health care provider.

''(c) ENFORCEMENT OF CERTAIN REQUIREMENTS.—

''(1) COMPLAINTS.—Any protected health care professional who believes that the professional has been retaliated or discriminated against in violation of section 135(b)(1) of the Bipartisan Patient Protection Act of 2001 may file with the Secretary a complaint within 180 days of the date of the alleged retaliation or discrimination.

''(2) INVESTIGATION.—The Secretary shall investigate such complaints and shall determine if a violation of such section has occurred and, if so, shall issue an order to ensure that the protected health care professional does not suffer any loss of position, pay, or benefits in relation to the plan, issuer, or provider involved, as a result of the violation found by the Secretary.

''(d) CONFORMING REGULATIONS.—The Secretary shall issue regulations to coordinate the requirements on group health plans and health insurance issuers under this section with the requirements imposed under the other provisions of this title. In order to reduce duplication and clarify the rights of participants and beneficiaries with respect to information that is required to be provided, such regulations shall coordinate the information disclosure requirements under section 121 of the Bipartisan Patient Protection Act of 2001 with the reporting and disclosure requirements imposed under part 1, so long as such coordination does not result in any reduction in the information that would otherwise be provided to participants and beneficiaries.''.

(b) SATISFACTION OF ERISA CLAIMS PROCEDURE REQUIREMENT.—Section 503 of such Act (29 U.S.C. 1133) is amended by inserting ''(a)'' after ''SEC. 503.'' and by adding at the end the following new subsection:

''(b) In the case of a group health plan (as defined in section 733) compliance with the requirements of subtitle A of title I of the Bipartisan Patient Protection Act of 2001, and compliance with regulations promulgated by the Secretary, in the case of a claims denial shall be deemed compliance with subsection (a) with respect to such claims denial.''.

(c) CONFORMING AMENDMENTS.—(1) Section 732(a) of such Act (29 U.S.C. 1185(a)) is amended by striking ''section 711'' and inserting ''sections 711 and 714''.

(2) The table of contents in section 1 of such Act is amended by inserting after the item relating to section 713 the following new item:

''Sec. 714. Patient protection standards.''.

(3) Section 502(b)(3) of such Act (29 U.S.C. 1132(b)(3)) is amended by inserting ''(other than section 135(b))'' after ''part 7''.

SEC. 302. AVAILABILITY OF CIVIL REMEDIES.

(a) AVAILABILITY OF FEDERAL CIVIL REMEDIES IN CASES NOT INVOLVING MEDICALLY REVIEWABLE DECISIONS.—

(1) IN GENERAL.—Section 502 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1132) is amended by adding at the end the following new subsection:

''(n) CAUSE OF ACTION RELATING TO PROVISION OF HEALTH BENEFITS.—

''(1) IN GENERAL.—In any case in which—

''(A) a person who is a fiduciary of a group health plan, a health insurance issuer offering health insurance coverage in connection with the plan, or an agent of the plan, issuer, or plan sponsor—

''(i) upon consideration of a claim for benefits of a participant or beneficiary under section 102 of the Bipartisan Patient Protection Act of 2001 (relating to procedures for initial claims for benefits and prior authorization determinations) or upon review of a denial of such a claim under section 103 of such Act (relating to internal appeal of a denial of a claim for benefits), fails to exercise ordinary care in making a decision—

''(I) regarding whether an item or service is covered under the terms and conditions of the plan or coverage,

''(II) regarding whether an individual is a participant or beneficiary who is enrolled under the terms and conditions of the plan or coverage (including the applicability of any waiting period under the plan or coverage), or

''(III) as to the application of cost-sharing requirements or the application of a specific exclusion or ex-

press limitation on the amount, duration, or scope of coverage of items or services under the terms and conditions of the plan or coverage, or

"(ii) otherwise fails to exercise ordinary care in the performance of a duty under the terms and conditions of the plan with respect to a participant or beneficiary, and

"(B) such failure is a proximate cause of personal injury to, or the death of, the participant or beneficiary,

such person shall be liable to the participant or beneficiary (or the estate of such participant or beneficiary) for economic and noneconomic damages (but not exemplary or punitive damages) in connection with such personal injury or death.

"(2) CAUSE OF ACTION MUST NOT INVOLVE MEDICALLY REVIEWABLE DECISION.—

"(A) IN GENERAL.—A cause of action is established under paragraph (1)(A) only if the decision referred to in clause (i) or the failure described in clause (ii) does not include a medically reviewable decision.

''(B) MEDICALLY REVIEWABLE DECISION.—For purposes of subparagraph (A), the term 'medically reviewable decision' means a denial of a claim for benefits under the plan which is described in section 104(d)(2) of the Bipartisan Patient Protection Act of 2001 (relating to medically reviewable decisions).

''(3) DEFINITIONS.—For purposes of this subsection.—

''(A) ORDINARY CARE.—The term 'ordinary care' means—

''(i) with respect to a determination on a claim for benefits, that degree of care, skill, and diligence that a reasonable and prudent individual would exercise in making a fair determination on a claim for benefits of like kind to the claim involved; and

''(ii) with respect to the performance of a duty, that degree of care, skill, and diligence that a reasonable and prudent individual would exercise in performing the duty or a duty of like character.

''(B) PERSONAL INJURY.—The term 'personal injury' means a physical injury and in-

cludes an injury arising out of the treatment (or failure to treat) a mental illness or disease.

"(C) CLAIM FOR BENEFITS; DENIAL.—The terms 'claim for benefits' and 'denial of a claim for benefits' have the meanings provided such terms in section 102(e) of the Bipartisan Patient Protection Act of 2001.

"(D) TERMS AND CONDITIONS.—The term 'terms and conditions' includes, with respect to a group health plan or health insurance coverage, requirements imposed under title I of the Bipartisan Patient Protection Act of 2001 or under part 6 or 7.

"(E) GROUP HEALTH PLAN AND OTHER RELATED TERMS.—The provisions of sections 732(d) and 733 apply for purposes of this subsection in the same manner as they apply for purposes of part 7, except that the term 'group health plan' includes a group health plan (as defined in section 607(1)).

"(4) EXCLUSION OF EMPLOYERS AND OTHER PLAN SPONSORS.—

"(A) CAUSES OF ACTION AGAINST EMPLOYERS AND PLAN SPONSORS PRECLUDED.—Subject to subparagraph (B), paragraph (1)(A)

does not authorize a cause of action against an employer or other plan sponsor maintaining the plan (or against an employee of such an employer or sponsor acting within the scope of employment).

''(B) CERTAIN CAUSES OF ACTION PERMITTED.—Notwithstanding subparagraph (A), a cause of action may arise against an employer or other plan sponsor (or against an employee of such an employer or sponsor acting within the scope of employment)—

''(i) under clause (i) of paragraph (1)(A), to the extent there was direct participation by the employer or other plan sponsor (or employee) in the decision of the plan under section 102 of the Bipartisan Patient Protection Act of 2001 upon consideration of a claim for benefits or under section 103 of such Act upon review of a denial of a claim for benefits, or

''(ii) under clause (ii) of paragraph (1)(A), to the extent there was direct participation by the employer or other plan sponsor (or employee) in the failure described in such clause.

"(C) DIRECT PARTICIPATION.—

"(i) DIRECT PARTICIPATION IN DECISIONS.—For purposes of subparagraph (B), the term 'direct participation' means, in connection with a decision described in clause (i) of paragraph (1)(A) or a failure described in clause (ii) of such paragraph, the actual making of such decision or the actual exercise of control in making such decision or in the conduct constituting the failure.

"(ii) RULES OF CONSTRUCTION.—For purposes of clause (i), the employer or plan sponsor (or employee) shall not be construed to be engaged in direct participation because of any form of decisionmaking or other conduct that is merely collateral or precedent to the decision described in clause (i) of paragraph (1)(A) on a particular claim for benefits of a participant or beneficiary or that is merely collateral or precedent to the conduct constituting a failure described in clause (ii) of paragraph (1)(A) with respect to a particular partici-

pant or beneficiary, including (but not limited to)—

"(I) any participation by the employer or other plan sponsor (or employee) in the selection of the group health plan or health insurance coverage involved or the third party administrator or other agent;

"(II) any engagement by the employer or other plan sponsor (or employee) in any cost-benefit analysis undertaken in connection with the selection of, or continued maintenance of, the plan or coverage involved;

"(III) any participation by the employer or other plan sponsor (or employee) in the process of creating, continuing, modifying, or terminating the plan or any benefit under the plan, if such process was not substantially focused solely on the particular situation of the participant or beneficiary referred to in paragraph (1)(A); and

''(IV) any participation by the employer or other plan sponsor (or employee) in the design of any benefit under the plan, including the amount of copayment and limits connected with such benefit.

''(iv) IRRELEVANCE OF CERTAIN COLLATERAL EFFORTS MADE BY EMPLOYER OR PLAN SPONSOR.—For purposes of this subparagraph, an employer or plan sponsor shall not be treated as engaged in direct participation in a decision with respect to any claim for benefits or denial thereof in the case of any particular participant or beneficiary solely by reason of—

''(I) any efforts that may have been made by the employer or plan sponsor to advocate for authorization of coverage for that or any other participant or beneficiary (or any group of participants or beneficiaries), or

''(II) any provision that may have been made by the employer or plan sponsor for benefits which are not covered under the terms and con-

ditions of the plan for that or any other participant or beneficiary (or any group of participants or beneficiaries).

''(5) REQUIREMENT OF EXHAUSTION.—

''(A) IN GENERAL.—Except as provided in this paragraph, a cause of action may not be brought under paragraph (1) in connection with any denial of a claim for benefits of any individual until all administrative processes under sections 102 and 103 of the Bipartisan Patient Protection Act of 2001 (if applicable) have been exhausted.

''(B) LATE MANIFESTATION OF INJURY.—The requirements under subparagraph (A) for a cause of action in connection with any denial of a claim for benefits shall be deemed satisfied, notwithstanding any failure to timely commence review under section 103 with respect to the denial, if the personal injury is first known (or first reasonably should have been known) to the individual (or the death occurs) after the latest date by which the applicable requirements of subparagraph (A) can be met in connection with such denial.

''(C) OCCURRENCE OF IMMEDIATE AND IRREPARABLE HARM OR DEATH PRIOR TO COMPLETION OF PROCESS.—

''(i) IN GENERAL.—The requirements of subparagraph (A) shall not apply if the action involves an allegation that immediate and irreparable harm or death was, or would be, caused by the denial of a claim for benefits prior to the completion of the administrative processes referred to in subparagraph (A) with respect to such denial.

''(ii) CONSTRUCTION.—Nothing in clause (i) shall be construed to preclude—

''(I) continuation of such processes to their conclusion if so moved by any party, and

''(II) consideration in such action of the final decisions issued in such processes.

''(iii) DEFINITION.—In clause (i), the term 'irreparable harm', with respect to an individual, means an injury or condition that, regardless of whether the individual receives the treatment that is the subject

of the denial, cannot be repaired in a manner that would restore the individual to the individual's pre-injured condition.

''(D) RECEIPT OF BENEFITS DURING APPEALS PROCESS.—Receipt by the participant or beneficiary of the benefits involved in the claim for benefits during the pendency of any administrative processes referred to in subparagraph (A) or of any action commenced under this subsection—

''(i) shall not preclude continuation of all such administrative processes to their conclusion if so moved by any party, and

''(ii) shall not preclude any liability under subsection (a)(1)(C) and this subsection in connection with such claim.

The court in any action commenced under this subsection shall take into account any receipt of benefits during such administrative processes or such action in determining the amount of the damages awarded.

''(6) STATUTORY DAMAGES.—

''(A) IN GENERAL.—The remedies set forth in this subsection (n) shall be the exclu-

sive remedies for causes of action brought under this subsection.

"(B) ASSESSMENT OF CIVIL PENALTIES.—In addition to the remedies provided for in paragraph (1) (relating to the failure to provide contract benefits in accordance with the plan), a civil assessment, in an amount not to exceed $5,000,000, payable to the claimant may be awarded in any action under such paragraph if the claimant establishes by clear and convincing evidence that the alleged conduct carried out by the defendant demonstrated bad faith and flagrant disregard for the rights of the participant or beneficiary under the plan and was a proximate cause of the personal injury or death that is the subject of the claim.

"(7) LIMITATION OF ACTION.—Paragraph (1) shall not apply in connection with any action commenced after 3 years after the later of—

"(A) the date on which the plaintiff first knew, or reasonably should have known, of the personal injury or death resulting from the failure described in paragraph (1), or

"(B) the date as of which the requirements of paragraph (5) are first met.

''(8) TOLLING PROVISION.—The statute of limitations for any cause of action arising under State law relating to a denial of a claim for benefits that is the subject of an action brought in Federal court under this subsection shall be tolled until such time as the Federal court makes a final disposition, including all appeals, of whether such claim should properly be within the jurisdiction of the Federal court. The tolling period shall be determined by the applicable Federal or State law, whichever period is greater.

''(9) PURCHASE OF INSURANCE TO COVER LIABILITY.—Nothing in section 410 shall be construed to preclude the purchase by a group health plan of insurance to cover any liability or losses arising under a cause of action under subsection (a)(1)(C) and this subsection.

''(10) EXCLUSION OF DIRECTED RECORDKEEPERS.—

''(A) IN GENERAL.—Subject to subparagraph (C), paragraph (1) shall not apply with respect to a directed recordkeeper in connection with a group health plan.

''(B) DIRECTED RECORDKEEPER.—For purposes of this paragraph, the term 'directed

recordkeeper' means, in connection with a group health plan, a person engaged in directed recordkeeping activities pursuant to the specific instructions of the plan or the employer or other plan sponsor, including the distribution of enrollment information and distribution of disclosure materials under this Act or title I of the Bipartisan Patient Protection Act of 2001 and whose duties do not include making decisions on claims for benefits.

''(C) LIMITATION.—Subparagraph (A) does not apply in connection with any directed recordkeeper to the extent that the directed recordkeeper fails to follow the specific instruction of the plan or the employer or other plan sponsor.

''(11) NO EFFECT ON STATE LAW.—No provision of State law (as defined in section 514(c)(1)) shall be treated as superseded or otherwise altered, amended, modified, invalidated, or impaired by reason of the provisions of subsection (a)(1)(C) and this subsection.''.

(2) CONFORMING AMENDMENT.—Section 502(a)(1) of such Act (29 U.S.C. 1132(a)(1)) is amended—

(A) by striking ''or'' at the end of subparagraph (A);

(B) in subparagraph (B), by striking ''plan;'' and inserting ''plan, or''; and

(C) by adding at the end the following new subparagraph:

''(C) for the relief provided for in subsection (n) of this section.''.

(b) RULES RELATING TO ERISA PREEMPTION.—Section 514 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1144) is amended—

(1) by redesignating subsection (d) as subsection (f); and

(2) by inserting after subsection (c) the following new subsections:

''(d) PREEMPTION NOT TO APPLY TO CAUSES OF ACTION UNDER STATE LAW INVOLVING MEDICALLY REVIEWABLE DECISION.—

''(1) NON-PREEMPTION OF CERTAIN CAUSES OF ACTION.—

''(A) IN GENERAL.—Except as provided in this subsection, nothing in this title (including section 502) shall be construed to supersede or otherwise alter, amend, modify, invalidate, or impair any cause of action under State law of

a participant or beneficiary under a group health plan (or the estate of such a participant or beneficiary) to recover damages resulting from personal injury or for wrongful death against any person if such cause of action arises by reason of a medically reviewable decision.

''(B) MEDICALLY REVIEWABLE DECISION.—For purposes of subparagraph (A), the term 'medically reviewable decision' means a denial of a claim for benefits under the plan which is described in section 104(d)(2) of the Bipartisan Patient Protection Act of 2001 (relating to medically reviewable decisions).

''(C) LIMITATION ON PUNITIVE DAMAGES.—

''(i) IN GENERAL.—Except as provided in clauses (ii) and (iii), with respect to a cause of action described in subparagraph (A) brought with respect to a participant or beneficiary, State law is superseded insofar as it provides any punitive, exemplary, or similar damages if, as of the time of the personal injury or death, all the requirements of the following sections

of the Bipartisan Patient Protection Act of 2001 were satisfied with respect to the participant or beneficiary:

"(I) Section 102 (relating to procedures for initial claims for benefits and prior authorization determinations).

"(II) Section 103 of such Act (relating to internal appeals of claims denials).

"(III) Section 104 of such Act (relating to independent external appeals procedures).

"(ii) EXCEPTION FOR CERTAIN ACTIONS FOR WRONGFUL DEATH.—Clause (i) shall not apply with respect to an action for wrongful death if the applicable State law provides (or has been construed to provide) for damages in such an action which are only punitive or exemplary in nature.

"(iii) EXCEPTION FOR WILLFUL OR WANTON DISREGARD FOR THE RIGHTS OR SAFETY OF OTHERS.—Clause (i) shall not apply with respect to any cause of action described in subparagraph (A) if, in such

action, the plaintiff establishes by clear and convincing evidence that conduct carried out by the defendant with willful or wanton disregard for the rights or safety of others was a proximate cause of the personal injury or wrongful death that is the subject of the action.

''(2) DEFINITIONS.—For purposes of this subsection and subsection (e)—

''(A) GROUP HEALTH PLAN AND OTHER RELATED TERMS.—The provisions of sections 732(d) and 733 apply for purposes of this subsection in the same manner as they apply for purposes of part 7, except that the term 'group health plan' includes a group health plan (as defined in section 607(1)).

''(B) PERSONAL INJURY.—The term 'personal injury' means a physical injury and includes an injury arising out of the treatment (or failure to treat) a mental illness or disease.

''(C) CLAIM FOR BENEFIT; DENIAL.—The terms 'claim for benefits' and 'denial of a claim for benefits' shall have the meaning provided such terms under section 102(e) of the Bipartisan Patient Protection Act of 2001.

''(3) EXCLUSION OF EMPLOYERS AND OTHER PLAN SPONSORS.—

''(A) CAUSES OF ACTION AGAINST EMPLOYERS AND PLAN SPONSORS PRECLUDED.—Subject to subparagraph (B), paragraph (1) does not apply with respect to—

''(i) any cause of action against an employer or other plan sponsor maintaining the plan (or against an employee of such an employer or sponsor acting within the scope of employment), or

''(ii) a right of recovery, indemnity, or contribution by a person against an employer or other plan sponsor (or such an employee) for damages assessed against the person pursuant to a cause of action to which paragraph (1) applies.

''(B) CERTAIN CAUSES OF ACTION PERMITTED.—Notwithstanding subparagraph (A), paragraph (1) applies with respect to any cause of action described in paragraph (1) maintained by a participant or beneficiary against an employer or other plan sponsor (or against an employee of such an employer or sponsor acting within the scope of employment)—

"(i) in the case of any cause of action based on a decision of the plan under section 102 of the Bipartisan Patient Protection Act of 2001 upon consideration of a claim for benefits or under section 103 of such Act upon review of a denial of a claim for benefits, to the extent there was direct participation by the employer or other plan sponsor (or employee) in the decision, or

"(ii) in the case of any cause of action based on a failure to otherwise perform a duty under the terms and conditions of the plan with respect to a claim for benefits of a participant or beneficiary, to the extent there was direct participation by the employer or other plan sponsor (or employee) in the failure.

"(C) DIRECT PARTICIPATION.—

"(i) DIRECT PARTICIPATION IN DECISIONS.—For purposes of subparagraph (B), the term 'direct participation' means, in connection with a decision described in subparagraph (B)(i) or a failure described in subparagraph (B)(ii), the actual making of such decision or the actual exercise of

control in making such decision or in the conduct constituting the failure.

''(ii) RULES OF CONSTRUCTION.—For purposes of clause (i), the employer or plan sponsor (or employee) shall not be construed to be engaged in direct participation because of any form of decisionmaking or other conduct that is merely collateral or precedent to the decision described in subparagraph (B)(i) on a particular claim for benefits of a particular participant or beneficiary or that is merely collateral or precedent to the conduct constituting a failure described in subparagraph (B)(ii) with respect to a particular participant or beneficiary, including (but not limited to)—

''(I) any participation by the employer or other plan sponsor (or employee) in the selection of the group health plan or health insurance coverage involved or the third party administrator or other agent;

''(II) any engagement by the employer or other plan sponsor (or employee) in any cost-benefit analysis

undertaken in connection with the selection of, or continued maintenance of, the plan or coverage involved;

''(III) any participation by the employer or other plan sponsor (or employee) in the process of creating, continuing, modifying, or terminating the plan or any benefit under the plan, if such process was not substantially focused solely on the particular situation of the participant or beneficiary referred to in paragraph (1)(A); and

''(IV) any participation by the employer or other plan sponsor (or employee) in the design of any benefit under the plan, including the amount of copayment and limits connected with such benefit.

''(iv) IRRELEVANCE OF CERTAIN COLLATERAL EFFORTS MADE BY EMPLOYER OR PLAN SPONSOR.—For purposes of this subparagraph, an employer or plan sponsor shall not be treated as engaged in direct participation in a decision with respect to

any claim for benefits or denial thereof in the case of any particular participant or beneficiary solely by reason of—

"(I) any efforts that may have been made by the employer or plan sponsor to advocate for authorization of coverage for that or any other participant or beneficiary (or any group of participants or beneficiaries), or

"(II) any provision that may have been made by the employer or plan sponsor for benefits which are not covered under the terms and conditions of the plan for that or any other participant or beneficiary (or any group of participants or beneficiaries).

"(4) REQUIREMENT OF EXHAUSTION.—

"(A) IN GENERAL.—Except as provided in this paragraph, paragraph (1) shall not apply with respect to a cause of action described in such paragraph in connection with any denial of a claim for benefits of any individual until all administrative processes under sections 102, 103, and 104 of the Bipartisan Patient Protec-

tion Act of 2001 (if applicable) have been exhausted.

''(B) LATE MANIFESTATION OF INJURY.—The requirements under subparagraph (A) for a cause of action in connection with any denial of a claim for benefits shall be deemed satisfied, notwithstanding any failure to timely commence review under section 103 or 104 with respect to the denial, if the personal injury is first known (or first should have been known) to the individual (or the death occurs) after the latest date by which the applicable requirements of subparagraph (A) can be met in connection with such denial.

''(C) OCCURRENCE OF IMMEDIATE AN IRREPARABLE HARM OR DEATH PRIOR TO COMPLETION OF PROCESS.—

''(i) IN GENERAL.—The requirements of subparagraph (A) shall not apply if the action involves an allegation that immediate and irreparable harm or death was, or would be, caused by the denial of a claim for benefits prior to the completion of the administrative processes referred to

in subparagraph (A) with respect to such denial.

''(ii) CONSTRUCTION.—Nothing in clause (i) shall be construed to preclude—

''(I) continuation of such processes to their conclusion if so moved by any party, and

''(II) consideration in such action of the final decisions issued in such processes.

''(iii) DEFINITION.—In clause (i), the term 'irreparable harm', with respect to an individual, means an injury or condition that, regardless of whether the individual receives the treatment that is the subject of the denial, cannot be repaired in a manner that would restore the individual to the individual's pre-injured condition.

''(D) RECEIPT OF BENEFITS DURING APPEALS PROCESS.—Receipt by the participant or beneficiary of the benefits involved in the claim for benefits during the pendency of any administrative processes referred to in subparagraph (A) or of any action commenced under this subsection—

"(i) shall not preclude continuation of all such administrative processes to their conclusion if so moved by any party, and

"(ii) shall not preclude any liability under subsection (a)(1)(C) and this subsection in connection with such claim.

"(5) TOLLING PROVISION.—The statute of limitations for any cause of action arising under section 502(n) relating to a denial of a claim for benefits that is the subject of an action brought in State court shall be tolled until such time as the State court makes a final disposition, including all appeals, of whether such claim should properly be within the jurisdiction of the State court. The tolling period shall be determined by the applicable Federal or State law, whichever period is greater.

"(6) EXCLUSION OF DIRECTED RECORDKEEPERS.—

"(A) IN GENERAL.—Subject to subparagraph (C), paragraph (1) shall not apply with respect to a directed recordkeeper in connection with a group health plan.

"(B) DIRECTED RECORDKEEPER.—For purposes of this paragraph, the term 'directed recordkeeper' means, in connection with a

group health plan, a person engaged in directed recordkeeping activities pursuant to the specific instructions of the plan or the employer or other plan sponsor, including the distribution of enrollment information and distribution of disclosure materials under this Act or title I of the Bipartisan Patient Protection Act of 2001 and whose duties do not include making decisions on claims for benefits.

''(C) LIMITATION.—Subparagraph (A) does not apply in connection with any directed recordkeeper to the extent that the directed recordkeeper fails to follow the specific instruction of the plan or the employer or other plan sponsor.

''(7) CONSTRUCTION.—Nothing in this subsection shall be construed as—

''(A) saving from preemption a cause of action under State law for the failure to provide a benefit for an item or service which is specifically excluded under the group health plan involved, except to the extent that—

''(i) the application or interpretation of the exclusion involves a determination described in section 104(d)(2) of the Bi-

partisan Patient Protection Act of 2001, or

"(ii) the provision of the benefit for the item or service is required under Federal law or under applicable State law consistent with subsection (b)(2)(B);

"(B) preempting a State law which requires an affidavit or certificate of merit in a civil action;

"(C) affecting a cause of action or remedy under State law in connection with the provision or arrangement of excepted benefits (as defined in section 733(c)), other than those described in section 733(c)(2)(A); or

"(D) affecting a cause of action under State law other than a cause of action described in paragraph (1)(A).

"(8) PURCHASE OF INSURANCE TO COVER LIABILITY.—Nothing in section 410 shall be construed to preclude the purchase by a group health plan of insurance to cover any liability or losses arising under a cause of action described in paragraph (1)(A).

''(e) RULES OF CONSTRUCTION RELATING TO HEALTH CARE.—Nothing in this title shall be construed as—

''(1) affecting any State law relating to the practice of medicine or the provision of medical care, or affecting any action based upon such a State law,

''(2) superseding any State law permitted under section 152(b)(1)(A) of the Bipartisan Patient Protection Act of 2001, or

''(3) affecting any applicable State law with respect to limitations on monetary damages.''.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to acts and omissions (from which a cause of action arises) occurring on or after the date of the enactment of this Act.

SEC. 303. LIMITATIONS ON ACTIONS.

Section 502 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1132) (as amended by section 302(a)) is amended further by adding at the end the following new subsection:

''(o) LIMITATIONS ON ACTIONS RELATING TO GROUP HEALTH PLANS.—

''(1) IN GENERAL.—Except as provided in paragraph (2), no action may be brought under subsection (a)(1)(B), (a)(2), or (a)(3) by a participant

or beneficiary seeking relief based on the application of any provision in section 101, subtitle B, or subtitle D of title I of the Bipartisan Patient Protection Act of 2001 (as incorporated under section 714).

''(2) CERTAIN ACTIONS ALLOWABLE.—An action may be brought under subsection (a)(1)(B), (a)(2), or (a)(3) by a participant or beneficiary seeking relief based on the application of section 101, 113, 114, 115, 116, 117, 118(a)(3), 119, or 120 of the Bipartisan Patient Protection Act of 2001 (as incorporated under section 714) to the individual circumstances of that participant or beneficiary, except that—

''(A) such an action may not be brought or maintained as a class action; and

''(B) in such an action, relief may only provide for the provision of (or payment of) benefits, items, or services denied to the individual participant or beneficiary involved (and for attorney's fees and the costs of the action, at the discretion of the court) and shall not provide for any other relief to the participant or beneficiary or for any relief to any other person.

''(3) OTHER PROVISIONS UNAFFECTED.—Nothing in this subsection shall be construed as affecting subsections (a)(1)(C) and (n) or section 514(d).

''(4) ENFORCEMENT BY SECRETARY UNAFFECTED.—Nothing in this subsection shall be construed as affecting any action brought by the Secretary.''.

TITLE IV—AMENDMENTS TO THE INTERNAL REVENUE CODE OF 1986

Subtitle A—Application of Patient Protection Provisions

SEC. 401. APPLICATION TO GROUP HEALTH PLANS UNDER THE INTERNAL REVENUE CODE OF 1986.

Subchapter B of chapter 100 of the Internal Revenue Code of 1986 is amended—

(1) in the table of sections, by inserting after the item relating to section 9812 the following new item:

''Sec. 9813. Standard relating to patients' bill of rights.'';

and

(2) by inserting after section 9812 the following:

"SEC. 9813. STANDARD RELATING TO PATIENTS' BILL OF RIGHTS.

"A group health plan shall comply with the requirements of title I of the Bipartisan Patient Protection Act of 2001 (as in effect as of the date of the enactment of such Act), and such requirements shall be deemed to be incorporated into this section.".

SEC. 402. CONFORMING ENFORCEMENT FOR WOMEN'S HEALTH AND CANCER RIGHTS.

Subchapter B of chapter 100 of the Internal Revenue Code of 1986, as amended by section 401, is further amended—

(1) in the table of sections, by inserting after the item relating to section 9813 the following new item:

"Sec. 9814. Standard relating to women's health and cancer rights.";

and

(2) by inserting after section 9813 the following:

"SEC. 9814. STANDARD RELATING TO WOMEN'S HEALTH AND CANCER RIGHTS.

"The provisions of section 713 of the Employee Retirement Income Security Act of 1974 (as in effect as of the date of the enactment of this section) shall apply to group health plans as if included in this subchapter.".

Subtitle B—Health Care Coverage Access Tax Incentives

SEC. 411. EXPANDED AVAILABILITY OF ARCHER MSAS.

(a) EXTENSION OF PROGRAM.—Paragraphs (2) and (3)(B) of section 220(i) of the Internal Revenue Code of 1986 (defining cut-off year) are each amended by striking ''2002'' each place it appears and inserting ''2004''.

(b) INCREASE IN NUMBER OF PERMITTED ACCOUNT PARTICIPANTS.—

(1) IN GENERAL.—Subsection (j) of section 220 of such Code is amended by redesignating paragraphs (3), (4), and (5) as paragraphs (4), (5), and (6) and by inserting after paragraph (2) the following new paragraph:

''(3) DETERMINATION OF WHETHER LIMIT EXCEEDED FOR YEARS AFTER 2001.—

''(A) IN GENERAL.—The numerical limitation for any year after 2001 is exceeded if the sum of—

''(i) the number of Archer MSA returns filed on or before April 15 of such calendar year for taxable years ending with or within the preceding calendar year, plus

''(ii) the Secretary's estimate (determined on the basis of the returns described

in clause (i)) of the number of Archer MSA returns for such taxable years which will be filed after such date, exceeds 1,000,000. For purposes of the preceding sentence, the term 'Archer MSA return' means any return on which any exclusion is claimed under section 106(b) or any deduction is claimed under this section.

''(B) ALTERNATIVE COMPUTATION OF LIMITATION.—The numerical limitation for any year after 2001 is also exceeded if the sum of—

''(i) 90 percent of the sum determined under subparagraph (A) for such calendar year, plus

''(ii) the product of 2.5 and the number of medical savings accounts established during the portion of such year preceding July 1 (based on the reports required under paragraph (5)) for taxable years beginning in such year,

exceeds 1,000,000''.

(2) CONFORMING AMENDMENTS.—

(A) Clause (ii) of section 220(j)(2)(B) of such Code is amended by striking ''paragraph (4)'' and inserting ''paragraph (5)''.

(B) Subparagraph (A) of section 220(j)(4) of such Code is amended by striking ''and 2001'' and inserting ''2001, 2002, and 2003''.

(c) INCREASE IN SIZE OF ELIGIBLE EMPLOYERS.—Subparagraph (A) of section 220(c)(4) of such Code is amended by striking ''50 or fewer employees'' and inserting ''100 or fewer employees''.

(d) EFFECTIVE DATE.—The amendments made by this section shall take effect on the date of the enactment of this Act.

(e) GAO STUDY.—Not later than 1 year after the date of the enactment of this Act, the Comptroller General of the United States shall prepare and submit a report to the Committee on Ways and Means of the House of Representatives and the Committee on Finance of the Senate on the impact of Archer MSAs on the cost of conventional insurance (especially in those areas where there are higher numbers of such accounts) and on adverse selection and health care costs.

SEC. 412. DEDUCTION FOR 100 PERCENT OF HEALTH INSURANCE COSTS OF SELF-EMPLOYED INDIVIDUALS.

(a) IN GENERAL.—Paragraph (1) of section 162(l) of the Internal Revenue Code of 1986 is amended to read as follows:

''(1) ALLOWANCE OF DEDUCTION.—In the case of an individual who is an employee within the meaning of section 401(c)(1), there shall be allowed as a deduction under this section an amount equal to 100 percent of the amount paid during the taxable year for insurance which constitutes medical care for the taxpayer and the taxpayer's spouse and dependents.''.

(b) EFFECTIVE DATE.—The amendment made by this section shall apply to taxable years beginning after December 31, 2001.

SEC. 413. CREDIT FOR HEALTH INSURANCE EXPENSES OF SMALL BUSINESSES.

(a) IN GENERAL.—Subpart D of part IV of subchapter A of chapter 1 of the Internal Revenue Code of 1986 (relating to business-related credits) is amended by adding at the end the following:

''SEC. 45E. SMALL BUSINESS HEALTH INSURANCE EXPENSES.

''(a) GENERAL RULE.—For purposes of section 38, in the case of a small employer, the health insurance credit determined under this section for the taxable year is an amount equal to the applicable percentage of the expenses paid by the taxpayer during the taxable year for health

insurance coverage for such year provided under a new health plan for employees of such employer.

''(b) APPLICABLE PERCENTAGE.—For purposes of subsection (a), the applicable percentage is—

''(1) in the case of insurance purchased as a member of a qualified health benefit purchasing coalition (as defined in section 9841), 30 percent, and

''(2) in the case of insurance not described in paragraph (1), 20 percent.

''(c) LIMITATIONS.—

''(1) PER EMPLOYEE DOLLAR LIMITATION.—The amount of expenses taken into account under subsection (a) with respect to any employee for any taxable year shall not exceed—

''(A) $2,000 in the case of self-only coverage, and

''(B) $5,000 in the case of family coverage.

In the case of an employee who is covered by a new health plan of the employer for only a portion of such taxable year, the limitation under the preceding sentence shall be an amount which bears the same ratio to such limitation (determined without regard to this sentence) as such portion bears to the entire taxable year.

''(2) PERIOD OF COVERAGE.—Expenses may be taken into account under subsection (a) only with respect to coverage for the 4-year period beginning on the date the employer establishes a new health plan.

''(d) DEFINITIONS.—For purposes of this section—

''(1) HEALTH INSURANCE COVERAGE.—The term 'health insurance coverage' has the meaning given such term by section 9832(b)(1).

''(2) NEW HEALTH PLAN.—

''(A) IN GENERAL.—The term 'new health plan' means any arrangement of the employer which provides health insurance coverage to employees if—

''(i) such employer (and any predecessor employer) did not establish or maintain such arrangement (or any similar arrangement) at any time during the 2 taxable years ending prior to the taxable year in which the credit under this section is first allowed, and

''(ii) such arrangement provides health insurance coverage to at least 70 percent of the qualified employees of such employer.

''(B) QUALIFIED EMPLOYEE.—

''(i) IN GENERAL.—The term 'qualified employee' means any employee of an employer if the annual rate of such employee's compensation (as defined in section 414(s)) exceeds $10,000.

''(ii) TREATMENT OF CERTAIN EMPLOYEES.—The term 'employee' shall include a leased employee within the meaning of section 414(n).

''(3) SMALL EMPLOYER.—The term 'small employer' has the meaning given to such term by section 4980D(d)(2); except that only qualified employees shall be taken into account.

''(e) SPECIAL RULES.—

''(1) CERTAIN RULES MADE APPLICABLE.—For purposes of this section, rules similar to the rules of section 52 shall apply.

''(2) AMOUNTS PAID UNDER SALARY REDUCTION ARRANGEMENTS.—No amount paid or incurred pursuant to a salary reduction arrangement shall be taken into account under subsection (a).

''(f) TERMINATION.—This section shall not apply to expenses paid or incurred by an employer with respect to

any arrangement established on or after January 1, 2010.''.

(b) CREDIT TO BE PART OF GENERAL BUSINESS CREDIT.—Section 38(b) of such Code (relating to current year business credit) is amended by striking ''plus'' at the end of paragraph (12), by striking the period at the end of paragraph (13) and inserting '', plus'', and by adding at the end the following:

''(14) in the case of a small employer (as defined in section 45E(d)(3)), the health insurance credit determined under section 45E(a).''.

(c) NO CARRYBACKS.—Subsection (d) of section 39 of such Code (relating to carryback and carryforward of unused credits) is amended by adding at the end the following:

''(10) NO CARRYBACK OF SECTION 45E CREDIT BEFORE EFFECTIVE DATE.—No portion of the unused business credit for any taxable year which is attributable to the employee health insurance expenses credit determined under section 45E may be carried back to a taxable year ending before the date of the enactment of section 45E.''.

(d) DENIAL OF DOUBLE BENEFIT.—Section 280C of such Code is amended by adding at the end the following new subsection:

''(d) CREDIT FOR SMALL BUSINESS HEALTH INSURANCE EXPENSES.—

''(1) IN GENERAL.—No deduction shall be allowed for that portion of the expenses (otherwise allowable as a deduction) taken into account in determining the credit under section 45E for the taxable year which is equal to the amount of the credit determined for such taxable year under section 45E(a).

''(2) CONTROLLED GROUPS.—Persons treated as a single employer under subsection (a) or (b) of section 52 shall be treated as 1 person for purposes of this section.''.

(e) CLERICAL AMENDMENT.—The table of sections for subpart D of part IV of subchapter A of chapter 1 of such Code is amended by adding at the end the following:

''Sec. 45E. Small business health insurance expenses.''.

(f) EFFECTIVE DATE.—The amendments made by this section shall apply to amounts paid or incurred in taxable years beginning after December 31, 2001, for arrangements established after the date of the enactment of this Act.

SEC. 414. CERTAIN GRANTS BY PRIVATE FOUNDATIONS TO QUALIFIED HEALTH BENEFIT PURCHASING COALITIONS.

(a) IN GENERAL.—Section 4942 of the Internal Revenue Code of 1986 (relating to taxes on failure to distribute income) is amended by adding at the end the following:

''(k) CERTAIN QUALIFIED HEALTH BENEFIT PURCHASING COALITION DISTRIBUTIONS.—

''(1) IN GENERAL.—For purposes of subsection (g), sections 170, 501, 507, 509, and 2522, and this chapter, a qualified health benefit purchasing coalition distribution by a private foundation shall be considered to be a distribution for a charitable purpose.

''(2) QUALIFIED HEALTH BENEFIT PURCHASING COALITION DISTRIBUTION.—For purposes of paragraph (1)—

''(A) IN GENERAL.—The term 'qualified health benefit purchasing coalition distribution' means any amount paid or incurred by a private foundation to or on behalf of a qualified health benefit purchasing coalition (as defined in section 9841) for purposes of payment or reimbursement of amounts paid or incurred in

connection with the establishment and maintenance of such coalition.

''(B) EXCLUSIONS.—Such term shall not include any amount used by a qualified health benefit purchasing coalition (as so defined)—

''(i) for the purchase of real property,

''(ii) as payment to, or for the benefit of, members (or employees or affiliates of such members) of such coalition, or

''(iii) for any expense paid or incurred more than 48 months after the date of establishment of such coalition.

''(3) TERMINATION.—This subsection shall not apply—

''(A) to qualified health benefit purchasing coalition distributions paid or incurred after December 31, 2009, and

''(B) with respect to start-up costs of a coalition which are paid or incurred after December 31, 2010.''.

(b) QUALIFIED HEALTH BENEFIT PURCHASING COALITION.—

(1) IN GENERAL.—Chapter 100 of such Code (relating to group health plan requirements) is

amended by adding at the end the following new subchapter:

"Subchapter D—Qualified Health Benefit Purchasing Coalition

"Sec. 9841. Qualified health benefit purchasing coalition.

"SEC. 9841. QUALIFIED HEALTH BENEFIT PURCHASING COALITION.

"(a) IN GENERAL.—A qualified health benefit purchasing coalition is a private not-for-profit corporation which—

"(1) sells health insurance through State licensed health insurance issuers in the State in which the employers to which such coalition is providing insurance are located, and

"(2) establishes to the Secretary, under State certification procedures or other procedures as the Secretary may provide by regulation, that such coalition meets the requirements of this section.

"(b) BOARD OF DIRECTORS.—

"(1) IN GENERAL.—Each purchasing coalition under this section shall be governed by a Board of Directors.

"(2) ELECTION.—The Secretary shall establish procedures governing election of such Board.

''(3) MEMBERSHIP.—The Board of Directors shall—

''(A) be composed of representatives of the members of the coalition, in equal number, including small employers and employee representatives of such employers, but

''(B) not include other interested parties, such as service providers, health insurers, or insurance agents or brokers which may have a conflict of interest with the purposes of the coalition.

''(c) MEMBERSHIP OF COALITION.—

''(1) IN GENERAL.—A purchasing coalition shall accept all small employers residing within the area served by the coalition as members if such employers request such membership.

''(2) OTHER MEMBERS.—The coalition, at the discretion of its Board of Directors, may be open to individuals and large employers.

''(3) VOTING.—Members of a purchasing coalition shall have voting rights consistent with the rules established by the State.

''(d) DUTIES OF PURCHASING COALITIONS.—Each purchasing coalition shall—

''(1) enter into agreements with small employers (and, at the discretion of its Board, with individuals and other employers) to provide health insurance benefits to employees and retirees of such employers,

''(2) where feasible, enter into agreements with 3 or more unaffiliated, qualified licensed health plans, to offer benefits to members,

''(3) offer to members at least 1 open enrollment period of at least 30 days per calendar year,

''(4) serve a significant geographical area and market to all eligible members in that area, and

''(5) carry out other functions provided for under this section.

''(e) LIMITATION ON ACTIVITIES.—A purchasing coalition shall not—

''(1) perform any activity (including certification or enforcement) relating to compliance or licensing of health plans,

''(2) assume insurance or financial risk in relation to any health plan, or

''(3) perform other activities identified by the State as being inconsistent with the performance of its duties under this section.

''(f) ADDITIONAL REQUIREMENTS FOR PURCHASING COALITIONS.—As provided by the Secretary in regulations, a purchasing coalition shall be subject to requirements similar to the requirements of a group health plan under this chapter.

''(g) RELATION TO OTHER LAWS.—

''(1) PREEMPTION OF STATE FICTITIOUS GROUP LAWS.—Requirements (commonly referred to as fictitious group laws) relating to grouping and similar requirements for health insurance coverage are preempted to the extent such requirements impede the establishment and operation of qualified health benefit purchasing coalitions.

''(2) ALLOWING SAVINGS TO BE PASSED THROUGH.—Any State law that prohibits health insurance issuers from reducing premiums on health insurance coverage sold through a qualified health benefit purchasing coalition to reflect administrative savings is preempted. This paragraph shall not be construed to preempt State laws that impose restrictions on premiums based on health status, claims history, industry, age, gender, or other underwriting factors.

''(3) NO WAIVER OF HIPAA REQUIREMENTS.—Nothing in this section shall be construed to change

the obligation of health insurance issuers to comply with the requirements of title XXVII of the Public Health Service Act with respect to health insurance coverage offered to small employers in the small group market through a qualified health benefit purchasing coalition.

''(h) DEFINITION OF SMALL EMPLOYER.—For purposes of this section—

''(1) IN GENERAL.—The term 'small employer' means, with respect to any calendar year, any employer if such employer employed an average of at least 2 and not more than 50 qualified employees on business days during either of the 2 preceding calendar years. For purposes of the preceding sentence, a preceding calendar year may be taken into account only if the employer was in existence throughout such year.

''(2) EMPLOYERS NOT IN EXISTENCE IN PRECEDING YEAR.—In the case of an employer which was not in existence throughout the 1st preceding calendar year, the determination under paragraph (1) shall be based on the average number of qualified employees that it is reasonably expected such employer will employ on business days in the current calendar year.''.

(2) CONFORMING AMENDMENT.—The table of subchapters for chapter 100 of such Code is amended by adding at the end the following item:

''Subchapter D. Qualified health benefit purchasing coalition.''.

(c) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to taxable years beginning after December 31, 2001.

SEC. 415. STATE GRANT PROGRAM FOR MARKET INNOVATION.

(a) IN GENERAL.—The Secretary of Health and Human Services (in this section referred to as the ''Secretary'') shall establish a program (in this section referred to as the ''program'') to award demonstration grants under this section to States to allow States to demonstrate the effectiveness of innovative ways to increase access to health insurance through market reforms and other innovative means. Such innovative means may include (and are not limited to) any of the following:

(1) Alternative group purchasing or pooling arrangements, such as a purchasing cooperatives for small businesses, reinsurance pools, or high risk pools.

(2) Individual or small group market reforms.

(3) Consumer education and outreach.

(4) Subsidies to individuals, employers, or both, in obtaining health insurance.

(b) SCOPE; DURATION.—The program shall be limited to not more than 10 States and to a total period of 5 years, beginning on the date the first demonstration grant is made.

(c) CONDITIONS FOR DEMONSTRATION GRANTS.—

(1) IN GENERAL.—The Secretary may not provide for a demonstration grant to a State under the program unless the Secretary finds that under the proposed demonstration grant—

(A) the State will provide for demonstrated increase of access for some portion of the existing uninsured population through a market innovation (other than merely through a financial expansion of a program initiated before the date of the enactment of this Act);

(B) the State will comply with applicable Federal laws;

(C) the State will not discriminate among participants on the basis of any health status-related factor (as defined in section 2791(d)(9) of the Public Health Service Act), except to the extent a State wishes to focus on populations that otherwise would not obtain health insurance because of such factors; and

(D) the State will provide for such evaluation, in coordination with the evaluation required under subsection (d), as the Secretary may specify.

(2) APPLICATION.—The Secretary shall not provide a demonstration grant under the program to a State unless—

(A) the State submits to the Secretary such an application, in such a form and manner, as the Secretary specifies;

(B) the application includes information regarding how the demonstration grant will address issues such as governance, targeted population, expected cost, and the continuation after the completion of the demonstration grant period; and

(C) the Secretary determines that the demonstration grant will be used consistent with this section.

(3) FOCUS.—A demonstration grant proposal under section need not cover all uninsured individuals in a State or all health care benefits with respect to such individuals.

(d) EVALUATION.—The Secretary shall enter into a contract with an appropriate entity outside the Depart-

ment of Health and Human Services to conduct an overall evaluation of the program at the end of the program period. Such evaluation shall include an analysis of improvements in access, costs, quality of care, or choice of coverage, under different demonstration grants.

(e) OPTION TO PROVIDE FOR INITIAL PLANNING GRANTS.—Notwithstanding the previous provisions of this section, under the program the Secretary may provide for a portion of the amounts appropriated under subsection (f) (not to exceed $5,000,000) to be made available to any State for initial planning grants to permit States to develop demonstration grant proposals under the previous provisions of this section.

(f) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated $100,000,000 for each fiscal year to carry out this section. Amounts appropriated under this subsection shall remain available until expended.

(g) STATE DEFINED.—For purposes of this section, the term ''State'' has the meaning given such term for purposes of title XIX of the Social Security Act.

TITLE V—EFFECTIVE DATES; COORDINATION IN IMPLEMENTATION

SEC. 501. EFFECTIVE DATES.

(a) GROUP HEALTH COVERAGE.—

(1) IN GENERAL.—Subject to paragraph (2) and subsection (d), the amendments made by sections 201(a), 301, 303, and 401 and 402 (and title I insofar as it relates to such sections) shall apply with respect to group health plans, and health insurance coverage offered in connection with group health plans, for plan years beginning on or after January 1, 2002 (in this section referred to as the ''general effective date'').

(2) TREATMENT OF COLLECTIVE BARGAINING AGREEMENTS.—In the case of a group health plan maintained pursuant to one or more collective bargaining agreements between employee representatives and one or more employers ratified before the date of the enactment of this Act, the amendments made by sections 201(a), 301, 303, and 401 and 402 (and title I insofar as it relates to such sections) shall not apply to plan years beginning before the later of—

(A) the date on which the last collective bargaining agreements relating to the plan terminates (determined without regard to any extension thereof agreed to after the date of the enactment of this Act); or

(B) the general effective date.

For purposes of subparagraph (A), any plan amendment made pursuant to a collective bargaining agreement relating to the plan which amends the plan solely to conform to any requirement added by this division shall not be treated as a termination of such collective bargaining agreement.

(b) INDIVIDUAL HEALTH INSURANCE COVERAGE.—Subject to subsection (d), the amendments made by section 202 shall apply with respect to individual health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market on or after the general effective date.

(c) TREATMENT OF RELIGIOUS NONMEDICAL PROVIDERS.—

(1) IN GENERAL.—Nothing in this Act (or the amendments made thereby) shall be construed to—

(A) restrict or limit the right of group health plans, and of health insurance issuers of-

fering health insurance coverage, to include as providers religious nonmedical providers;

(B) require such plans or issuers to—

(i) utilize medically based eligibility standards or criteria in deciding provider status of religious nonmedical providers;

(ii) use medical professionals or criteria to decide patient access to religious nonmedical providers;

(iii) utilize medical professionals or criteria in making decisions in internal or external appeals regarding coverage for care by religious nonmedical providers; or

(iv) compel a participant or beneficiary to undergo a medical examination or test as a condition of receiving health insurance coverage for treatment by a religious nonmedical provider; or

(C) require such plans or issuers to exclude religious nonmedical providers because they do not provide medical or other required data, if such data is inconsistent with the religious nonmedical treatment or nursing care provided by the provider.

(2) RELIGIOUS NONMEDICAL PROVIDER.—For purposes of this subsection, the term ''religious nonmedical provider'' means a provider who provides no medical care but who provides only religious nonmedical treatment or religious nonmedical nursing care.

(d) TRANSITION FOR NOTICE REQUIREMENT.—The disclosure of information required under section 121 of this Act shall first be provided pursuant to—

(1) subsection (a) with respect to a group health plan that is maintained as of the general effective date, not later than 30 days before the beginning of the first plan year to which title I applies in connection with the plan under such subsection; or

(2) subsection (b) with respect to a individual health insurance coverage that is in effect as of the general effective date, not later than 30 days before the first date as of which title I applies to the coverage under such subsection.

SEC. 502. COORDINATION IN IMPLEMENTATION.

The Secretary of Labor, the Secretary of Health and Human Services, and the Secretary of the Treasury shall ensure, through the execution of an interagency memorandum of understanding among such Secretaries, that—

(1) regulations, rulings, and interpretations issued by such Secretaries relating to the same matter over which such Secretaries have responsibility under the provisions of this division (and the amendments made thereby) are administered so as to have the same effect at all times; and

(2) coordination of policies relating to enforcing the same requirements through such Secretaries in order to have a coordinated enforcement strategy that avoids duplication of enforcement efforts and assigns priorities in enforcement.

SEC. 503. SEVERABILITY.

If any provision of this Act, an amendment made by this Act, or the application of such provision or amendment to any person or circumstance is held to be unconstitutional, the remainder of this Act, the amendments made by this Act, and the application of the provisions of such to any person or circumstance shall not be affected thereby.

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